

**“A PROSPECTIVE RANDOMIZED STUDY TO COMPARE  
INTRATHECAL ISOBARIC BUPIVACAINE WITH  
FENTANYL AND ISOBARIC ROPIVACAINE WITH  
FENTANYL IN PATIENTS UNDERGOING ELECTIVE  
ENDOSCOPIC UROLOGICAL PROCEDURES”**

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**INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE**

**MADRAS MEDICAL COLLEGE**

**CHENNAI - 600003**

**APRIL - 2015**

## **CERTIFICATE**

This is to certify that the dissertation entitled “**A PROSPECTIVE RANDOMIZED STUDY TO COMPARE INTRATHECAL ISOBARIC BUPIVACAINE WITH FENTANYL AND ISOBARIC ROPIVACAINE WITH FENTANYL IN PATIENTS UNDERGOING ELECTIVE ENDOSCOPIC UROLOGICAL PROCEDURES**” is a bonafide work done by **Dr. MUTHUKUMAR.T**, Post Graduate Student, Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai-3, in partial fulfillment of the University Rules and Regulations for the award of MD Branch – X Anaesthesiology, under our guidance and supervision, during the academic year 2012 – 2015.

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## **DECLARATION**

I solemnly declare that the dissertation entitled “**A PROSPECTIVE RANDOMIZED STUDY TO COMPARE INTRATHECAL ISOBARIC BUPIVACAINE WITH FENTANYL AND ISOBARIC ROPIVACAINE WITH FENTANYL IN PATIENTS UNDERGOING ELECTIVE ENDOSCOPIC UROLOGICAL PROCEDURES**” is done by me at Madras Medical College, Chennai-3 under the guidance and supervision of **Prof. Dr. ESTHER SUDHARSHINI RAJKUMAR, MD., DA**, to be submitted to The Tamilnadu Dr. M.G.R Medical University towards the partial fulfillment of requirements for the award of M.D Degree In Anaesthesiology Branch-X.

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# **INTRODUCTION**

## **INTRODUCTION**

August Bier first described "Cocainization of the spinal cord" in 1899. The technique has been modified since that time and has evolved into the modern concept of subarachnoid block (SAB).

Sub arachnoid block is preferred over general anaesthesia for endoscopic urological procedures, because it facilitates early identification of symptoms caused by overhydration, Trans Urethral Resection of Prostate syndrome and bladder perforation.

Commonly used local anaesthetic for sub arachnoid block is bupivacaine. But it has significant cardiotoxic properties. To overcome this side effect ropivacaine a long lasting drug with less cardiotoxicity was discovered.

Local anaesthetics are available as hypobaric, isobaric and hyperbaric solutions. Hyperbaric solutions are often used. They tend to settle in the dependant portion of the sac while isobaric solution will usually stay in vicinity where they are injected and diffuse slowly in all directions. Hence isobaric solutions produce less complications compared to hyperbaric.

Isobaric anaesthetic injected in L2-L3 inter vertebral space provides dense block at lower thoracic, lumbar and sacral areas. So it is ideally suited

for endoscopic urological procedures which needs block upto T10 level. It results in partial sympathetic block with minimum hemodynamic changes.

Most of patients presenting for endoscopic urological surgery are elderly, having co-morbidities like cardiac, pulmonary, renal or some other condition. To reduce the adverse effects associated with subarachnoid block in these patients, a suitable adjuvant to low dose local anesthetics can help to give the satisfactory spinal block without compromising safety.

Opioids are the commonly used adjuvants with local anaesthetics for intrathecal injections. They help to reduce the dosage of local anaesthetic without compromising the quality of analgesia. They also give better postoperative pain relief and so patient can be ambulated early which lowers the risk of postoperative venous thrombosis. The dose used for sub arachoid block is little compared to parenteral dose and it does not result in complications. Highly lipophilic drugs like fentanyl, sufentanil and alfentanil are more suitable than less lipophilic drugs like morphine. Fentanyl is the frequently used opioid.

In this prospective randomized control study, we are comparing the effects of intrathecal 0.5% isobaric bupivacaine with fentanyl and 0.5% isobaric ropivacaine with fentanyl in endoscopic urological procedures like Trans Urethral Resection of Prostate, Vesicolitholapaxy, Ureteroscopic Stone Lithotripsy and Optical Internal Urethrostomy.



# **AIMS AND OBJECTIVES**

## **AIMS AND OBJECTIVES**

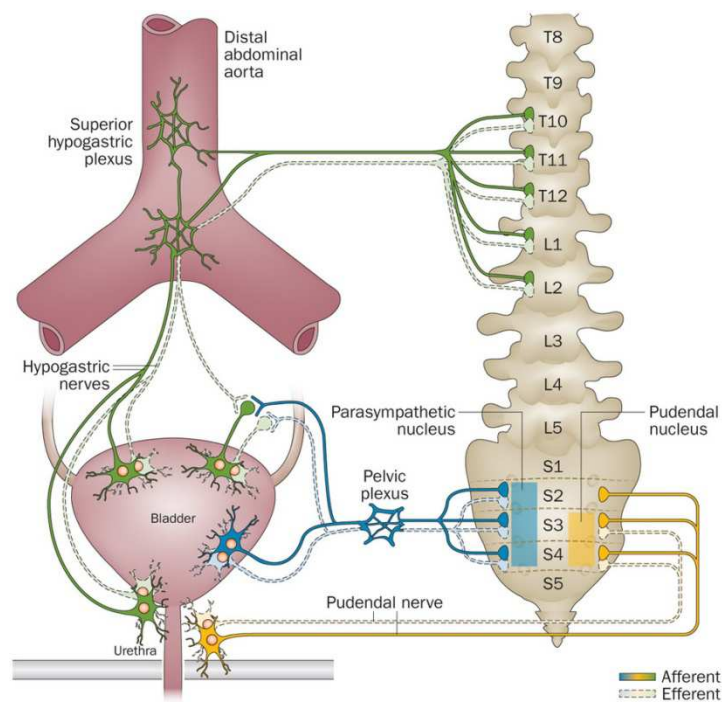
**To compare intrathecal isobaric bupivacaine with fentanyl and isobaric ropivacaine with fentanyl in patients undergoing elective endoscopic urological procedures with respect to**

1. Intraoperative hemodynamics.
2. To compare onset and duration of sensory and motor blockade.
3. Quality of analgesia.

**NEURO ANATOMY OF  
GENITO URINARY TRACT**

# NEUROANATOMY OF GENITOURINARY TRACT

Knowledge of neuroanatomy of genitourinary tract is important to appreciate the level of neuraxial block needed for urological procedures.



## KIDNEY

Afferent fibres run through celiac, renal and superior hypogastric plexuses and continue in the thoracic and lumbar splanchnic nerves. (T10-L1). Some afferent fibres also run with the vagus nerve. This explains the nausea and vomiting that occurs with renal pain.

## **URETER**

Sympathetic fibres to ureter originates from T10 through second lumbar segment. It synapses with post ganglionic fibres in aortic renal, superior and inferior hypogastric plexus. Parasympathetic is from S2, S3, S4 sacral spinal segment.

## **BLADDER AND URETHRA**

Sympathetic nerves to bladder and urethra originates from 11<sup>th</sup> thoracic to the 2<sup>nd</sup> lumbar segment through superior hypogastric plexus. Parasympathetic nerves arise from S2,S3,S4 segments and form pelvic parasympathetic plexus which is joined by hypogastric plexus.

Parasympathetic fibres are main motor supply to bladder except trigone of bladder. Parasympathetic afferent carries sensation of stretch and fullness of bladder whereas sympathetic carries pain, touch and temperature sensation.

## **PROSTATE**

Prostate gland receives sympathetic supply from T11 to L3 spinal segments and parasympathetic from S2,S3 and S4 sacral spinal segment.

## **PENIS, SCROTUM AND DISTAL URETHRA.**

Pudendal nerve (S2-S4) supplies penis, scrotum and distal urethra. The skin at the base of penis and on anterior aspect of scrotum are supplied by Ilioinguinal (L1) nerve and Genitofemoral (L1,L2) nerves.

<b>ORGAN</b>	<b>SYMPATHETIC</b>	<b>PARASYMPATHETIC</b>	<b>PAIN CONDUCTION LEVEL</b>
Ureter	T10-L2	S2,S3,S4	T10-L1
Bladder	T11-L2	S2,S3,S4	T10-L2
Prostate	T11-L2	S2,S3,S4	T11 L2 S2-S4

# **ANATOMY OF SUB ARACHNOID SPACE**

## ANATOMY OF SUBARACHNOID SPACE

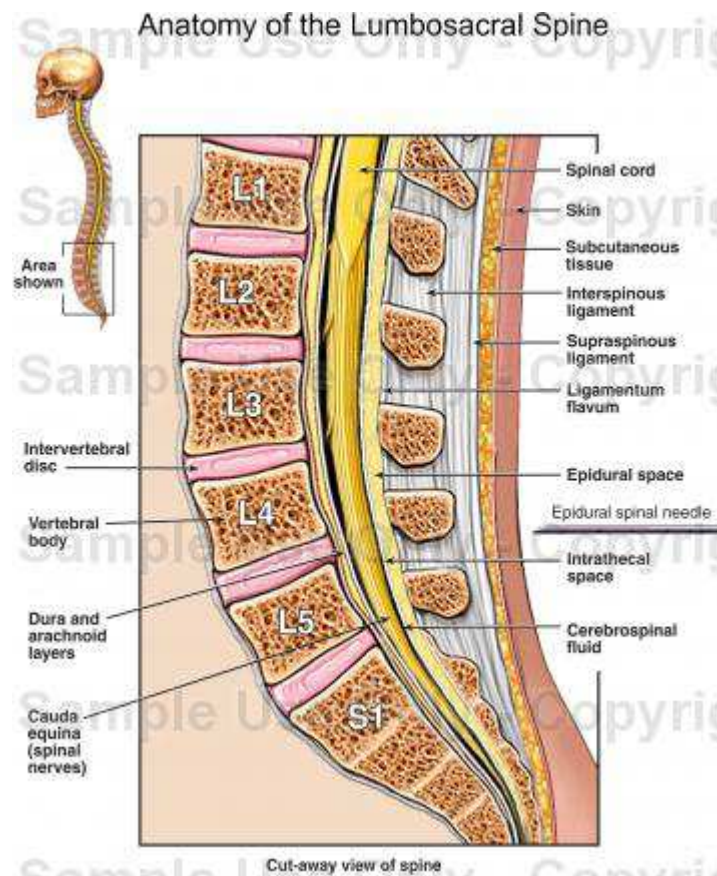
Sub arachnoid space also known as sub arachnoid cavity is a continuous space. It is the area between arachnoid mater and piamater. It extends from cerebral ventricles to sacral vertebra S2. Fibrous strands called trabeculae provides attachment between arachnoid and piamater.

## Contents:

## Cerebro Spinal Fluid

## Spinal cord

## Conus madullaris





Subarachnoid space has direct communication with brainstem through foramen magnum. So aseptic precautions should be followed as a must while performing lumbar puncture.

## **SPINAL CORD**

It lies between foramen magnum to level of first or second lumbar vertebra. It is 40-50cm long and 1-1.5cm thick. 31 pairs of spinal nerves emerge from spinal cord. They contain sensory and motor nerve fibres to and from all parts of body.

### **Membranes that surrounds spinal cord**

Spinal cord is surrounded by three meninges. They are Piamater- Innermost layer; it is highly vascular and covers spinal cord and brain. It attaches to the periosteum of coccyx.

Arachnoid mater-It lies outer to piamater. It is non vascular and attaches to duramater. It acts as a principle barrier to the migration of medications in and out of CSF.

### **Duramater:**

The dura mater is the outermost layer. It is present from the foramen magnum upto sacrum and coccyx. The dura is being separated by the epidural space into peridural and extradural space. They contain fat and the vertebral venous plexus. In caudal analgesia technique the drug is injected into the

sacral hiatus which diffuses upward into the epidural space. Dural sheath extends to cover the nerve roots and spinal ganglia and forms the epineurium of spinal nerves.

## **SUBDURAL SPACE**

It lies between dura arachnoid mater. It contains small amount of serous fluid that acts as lubricant. Inadvertant injection of medication into this space can lead to failed or total spinal.

## **BLOOD SUPPLY**

### **Anterior spinal artery**

Single anterior spinal artery is formed by vertebral artery at the base of skull. It supplies  $2/3^{\text{rd}}$  of anterior spinal cord.

### **Posterior spinal artery**

These are paired arteries. It is formed by posterior cerebellar arteries and travel down the dorsal surface of spinal cord just medial to dorsal nerves roots. They supply  $1/3^{\text{rd}}$  of posterior cord.

Additional supply-Intercostal and lumbar arteries.

## Artery of adamkiewicz

It is a radicular artery arising from Aorta. It is large, unilateral and left sided artery. It supplies lower anterior 2/3<sup>rd</sup> of spinal cord. Injury to this artery results in Spinal Artery Syndrome.

## Surface Anatomy

Understanding of surface anatomy is important to identify the correct intervertebral space to place the needle.

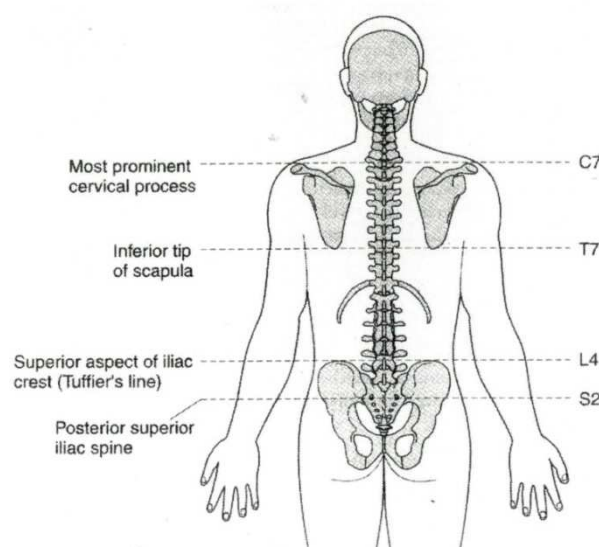
Prominent anatomical landmarks are

The first palpable spinous process is C2.

Most prominently felt vertebra is C7.

The tip of the scapula corresponds to T7 vertebra.

Tuffier's line corresponds to body of L4 vertebra or L4-L5 interspace.



## SURFACE LANDMARK FOR IDENTIFYING SPINAL LEVEL

## **TUFFIER'S LINE**

A line drawn between highest points of both iliac crests will yield either the body of L4 or L4-L5 interspace.

A line drawn across posterior superior iliac spine will cross S2.

## **Locating the midline.**

The palpable spinous processes defines midline.

If unable to palpate spinous process, gluteal crease may help to identify midline. This won't help if the patient has spinal abnormalities like scoliosis or kyphoscoliosis.

With flexion, spinous processes in the cervical and lumbar areas are almost horizontal. So needle should be placed slightly in cephalad direction.

## **STRUCTURES PIERCED BY SPINAL NEEDLE.**

1.SKIN-Infiltration of local anaesthetic will help to reduce the pain of piercing.

2.SUBCUTANEOUS TISSUE - It is of variable thickness in each patient. It is thick in obese and thin in lean patient. So identification of intervertebral space is difficult in obese patients.

3.SUPRASPINOUS LIGAMENT - The tips of spinous processes are joined by this ligament.

4. INTERSPINOUS LIGAMENT - This ligament is thin, flat and lies between spinous processes.

5.LIGAMENTUM FLAVUM - It is a thick ligament made of elastic tissue. It runs from lamina to lamina. In lumbar region, the distance from skin to ligament is around 3-8 cm, thickness is around 6-8mm. When the needle is within this ligament, it will feel gripped and a distinct “give away” is felt while piercing this layer.

6.EPIDURAL SPACE - It lies outer to dura mater. It contains fat and blood vessels. Bloody tap occurs because of piercing these epidural veins.

7.SUBARACHNOID SPACE - The contents of this space are spinal cord and nerve roots surrounded by CSF.

**CSF PHYSIOLOGY AND  
PHYSIOLOGICAL EFFECT OF  
SPINAL ANAESTHESIA**

# **CSF PHYSIOLOGY AND PHYSIOLOGICAL EFFECTS OF SPINAL ANAESTHESIA**

## **CSF PHYSIOLOGY**

CSF is produced by choroid plexus from arterial blood. It is situated within the fourth ventricle. It is produced by a combined process of diffusion, pinocytosis and active transport mechanism. It is also secreted by ependymal cells.

CSF flows from lateral ventricle to third ventricle and then through cerebral aqueduct to fourth ventricle. Circulation of CSF is helped by pulsation of choroid plexus and by motion of cilia of ependymal cells.

Absorption of CSF into venous circulation is through arachnoid villi. A small amount is also absorbed by lymphatic vessels around cranial cavity and spinal canal. Rate of absorption depends on pressure of CSF.

## **VOLUME AND PRESSURE.**

CSF is a clear, colourless, transparent fluid.

Total volume is around 150-300ml. Of which around 125 ml is present in intracranial compartment. Volume of ventricle is 25 ml. 100 ml is present in cranial subarachnoid space.

Rate of CSF production is 0.3 ml/min.

CSF pressure at lumbar puncture in lateral recumbent posture is 10-18 cm of H<sub>2</sub>O and 20-30 cm of H<sub>2</sub>O with sitting position.

Specific gravity of CSF is 1.003-1.009.

## **FUNCTIONS.**

It act as shock absorbant of brain.

It supports venous sinuses.

It maintains homeostasis and metabolism of CNS.

## **Physiological Effects of Spinal Anesthesia.**

Most of the physiological side effects of spinal anaesthesia are a consequence of the sympathetic blockade produced by local anesthetic block of the sympathetic fibers in the spinal nerve roots. Understanding of these physiological effects is necessary for the safe and successful application of spinal anesthesia. Although some of them may be deleterious and require treatment, others can be beneficial for the patient or can improve operating conditions.

Most sympathetic fibers leave the spinal cord between T1 and L2. Although local anesthetic is injected below these levels in the lumbar portion of the dural sac, cephalad spread of the local anesthetic occurs. This cephalad



spread is of considerable importance in the practice of spinal anesthesia and potentially is under the control of numerous variables, of which patient position and baricity (density of the drug relative to the density of the CSF) are the most important (Greene, 1983). The degree of sympathetic block is related to the height of sensory anesthesia; often the level of sympathetic blockade is several spinal segments higher, since the preganglionic sympathetic fibers are more sensitive to low concentrations of local anesthetic.

The effects of sympathetic blockade involve both the actions (now partially unopposed) of the parasympathetic nervous system and the response of the unblocked portion of the sympathetic nervous system. Thus, as the level of sympathetic block ascends, the actions of the parasympathetic nervous system are increasingly dominant, and the compensatory mechanisms of the unblocked sympathetic nervous system are diminished. As most sympathetic nerve fibers leave the cord at T1 or below, few additional effects of sympathetic blockade are seen with cervical levels of spinal anesthesia. The consequences of sympathetic blockade will vary among patients as a function of age, physical conditioning, and disease state.

**ANAESTHETIC  
CONSIDERATIONS OF SPINAL  
CORD AND NEURAXIAL  
BLOCKADE**

## **ANAESTHETIC CONSIDERATIONS OF SPINAL CORD AND NEURAXIAL BLOCKADE.**

In adults spinal cord usually ends at L1. In infants, it ends at L3. So it is safe to place spinal needle below L2 in adults.

### **MECHANISM OF ACTION OF SPINAL ANAESTHETIC.**

The anterior and posterior nerve roots pass through CSF. Local anaesthetics block autonomic, sensory and motor impulses. The sites of action are spinal nerve root and dorsal ganglion.

### **UPTAKE AND ELIMINATION.**

It depends on the following factors.

Concentration of local anaesthetic in CSF.

Surface area of neuronal tissue exposed to CSF.

Blood flow to the neuronal tissue.

Lipid content of tissue.

Spinal nerve roots are devoid of epineurium, so they are easily blocked. Though the site of action of local anaesthetic is not spinal cord, it

absorbs the drug into the pia mater and a space known as Virchow-Robbin which is an extension of sub arachnoid space.

Because of this absorption and dilution of drug by CSF, the concentration of the drug decreases as it moves away from the site of injection.

Initial vascular uptake of drug occurs in the blood vessels of pia mater and spinal cord. Local anaesthetic diffuses into the epidural space along a concentration gradient. From there, it is absorbed into epidural vasculature. The rate of absorption depends on the lipid solubility of the drug and the extent of surface area where it is exposed.

## **DIFFERENTIAL BLOCKADE.**

It refers to clinical phenomenon that nerve fibres with different functions have different sensitivity to local anaesthetic. This depends on factors like length of each nerve in thecal space, depth of nerve fibre, distribution of  $\text{Na}^+$ - $\text{K}^+$  channels on each nerve.

Sympathetic nerve fibres are blocked by lowest concentration of local anaesthetic followed by pain, temperature, touch, proprioception and finally motor.

Clinically observed sequence of block:

- 1.Sympathetic (B- fibres : Vasodilatation, skin temperature increases).
- 2.Temperature and pain conduction(A- delta and C-fibres).
- 3.Proprioception and touch (A- gamma and A -beta fibres).
- 4.Motor functions (A-delta fibres).

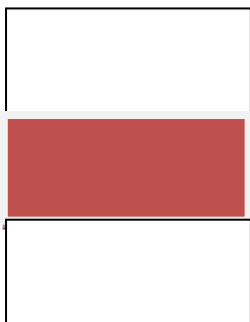
## **FACTORS AFFECTING LEVEL OF SPINAL BLOCK CHARECTERS OF INJECTED SOLUTION**

VOLUME / DOSE - Larger the volume higher the block.

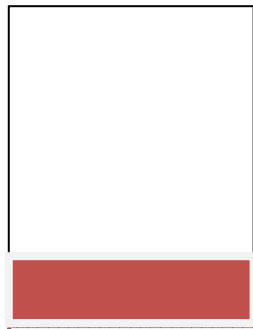
### **BARICITY**

Based on normal specific gravity of CSF (1.003-1.008) a local anaesthetic solution may be hypobaric, isobaric or hyperbaric.

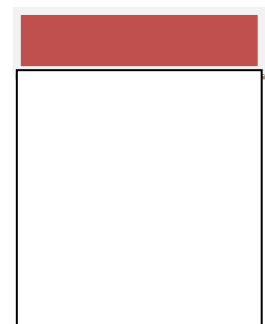
#### **ISOBARIC**



#### **HYPERBARIC**



#### **HYPOBARIC**



Hyperbaric means the solution is heavier than the CSF. It is generally prepared by adding dextrose to local anaesthetic. In head up position hyperbaric solution will settle down caudally. It is the most commonly used form.

Hypobaric solutions are lighter than the CSF. They move in cephalad direction. This can be prepared by adding sterile water to local anaesthetic.

Isobaric solution generally have same specific gravity as CSF. Generally it will stay within the area of injection. Isobaric solution may be prepared by mixing local anaesthetic solution with CSF in a 1:1 ratio.

**CONCENTRATION** - Higher the concentration greater the block.

**TEMPERATURE** - Very minor role, but if the solution is cold it will be more viscous and spread less; the opposite is true for warm solution.

## **PATIENT CHARACTERISTICS.**

**AGE**- Minor role; anatomical changes as ages may raise the height of block.

## **FACTORS INFLUENCING SPINAL LEVEL IN OLDER AGE.**

1. Volume of CSF is decreased.
2. Permeability of dura is increased.

3. Myelinated fibres decrease in size and number in the dorsal and ventral nerve roots.

4. Narrowing of intervertebral space and osteophytes growth decreases transforaminal escape of local anaesthetic. This increases level of block.

5. Increased permeability of extra neural tissue to local anaesthetic.

All the above factors reduce the requirement of dose of local anaesthetic in older age.

**HEIGHT**- Minor role, unless extremes.

## **INTRA ABDOMINAL PRESSURE**

Engorgement of epidural veins causes a decrease in CSF volume which results in higher block. Conditions that may increase intra abdominal pressure are: pregnancy, obesity, ascites and abdominal tumours.

## **SPINAL ANATOMY**

Normal anatomical curvature influences the spread of hyperbaric solution. This includes natural lordosis and natural thoracic kyphosis.

When the drug is injected above L3 with patient in supine position, the drug will spread cephalad upto T4 which limits its spread.

## **PREGNANCY**

Exaggerated lumbar lordosis in pregnancy reduces the sub arachnoid space volume. Also the parturients have increased sensitivity to local anaesthetic because of progesterone. So dose of local anaesthetic should be decreased to 1/3 in full term parturients.

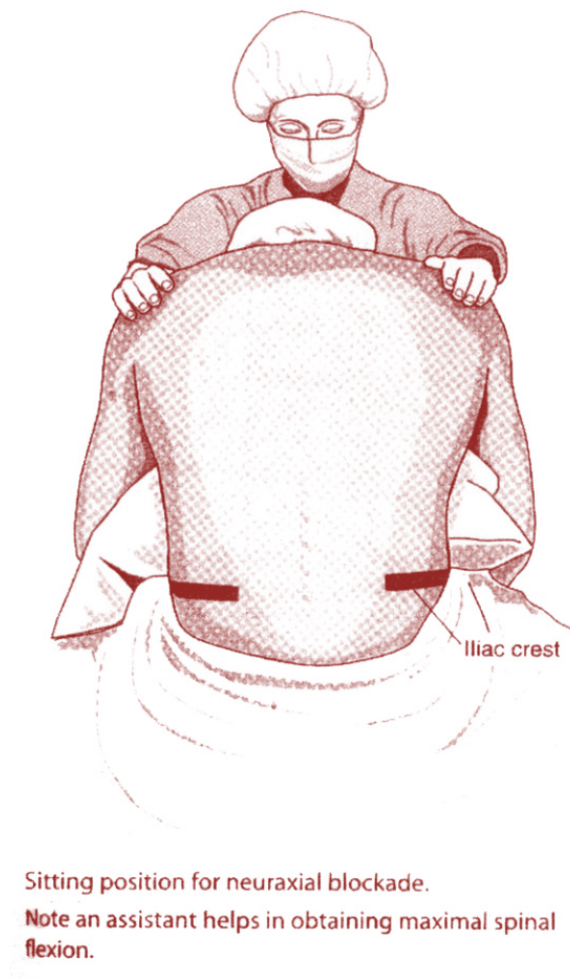
Abnormal changes in anatomy of spine may decrease CSF volume and thereby increasing height of block. Conditions include kyphosis, kyphoscoliosis and lordosis.



## **CLINICAL TECHNIQUE.**

### **PATIENT POSITION**

Patient position during administration and immediately after administration will impact block level. This is largely the function of baricity of anaesthetic solution.

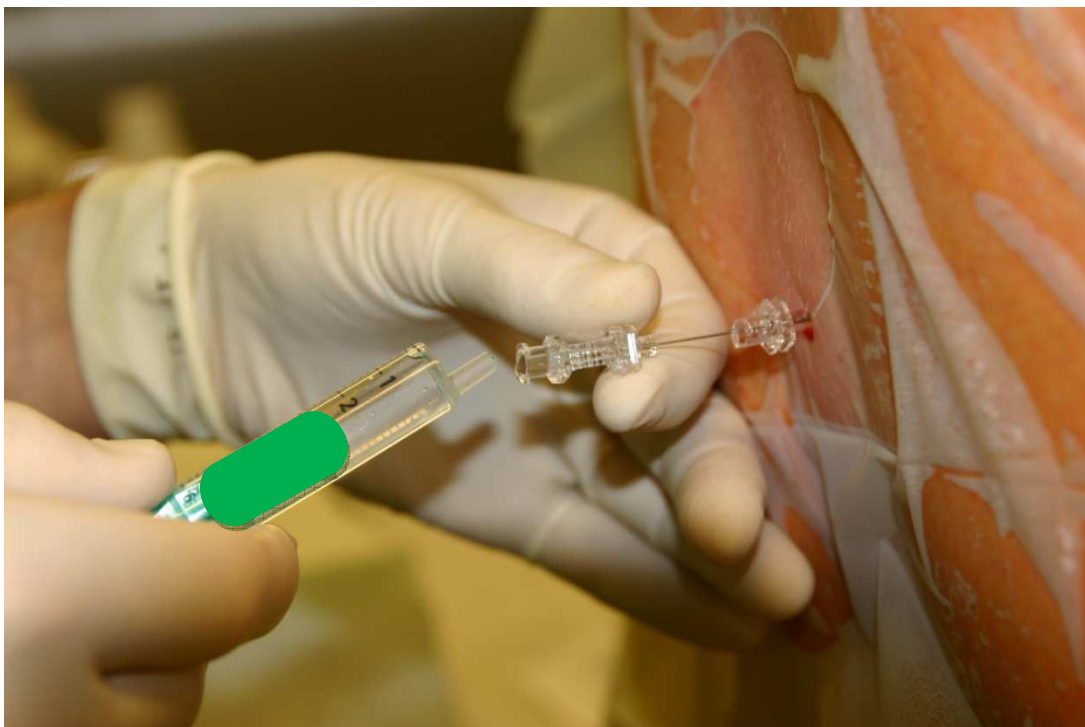


### **LEVEL OF INJECTION.**

The level of injection will influence spread. A greater spread will occur if injected at L2-L3 as opposed to L5-S1.

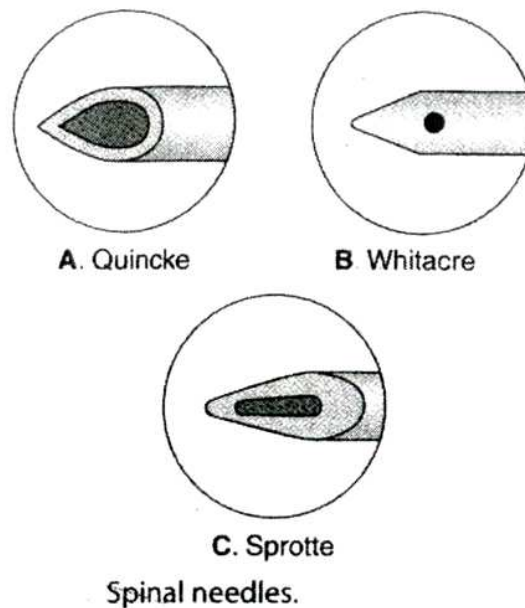
## TECHNIQUE OF INJECTION

**Direction of needle-** If the bevel of the needle is facing in cephalad direction and the drug injected will spread more than when the bevel is facing in lateral or caudal direction. coughing, straining or barbotage does not affect the height of block.



## SPINAL NEEDLE TYPE AND SIZE

Spinal needles are available in various sizes(16-30 gauge).Smaller needles are used in younger patients (22-25 gauge) and more thinner needles (25-27 gauge) are often used in older individuals which reduce the incidence of post dural puncture headache.



Spinal needles are blunt or cutting tipped. Pencil point or blunt tipped needles decrease the incidence of post puncture headache. Whitacre needle is an example for pencil point type with rounded point and side bore. Quincke needle is an example for cutting needle with end bore. Sprotte is a side bored needle with a long opening. It has advantage of more CSF flow. Its disadvantage is that it can cause failed spinal.

### **CHARACTERISTICS OF SPINAL FLUID.**

Volume and density of spinal fluid will affect the height of block.

CSF volume is inversely related to height of block. Decreased volumes will have a greater spread.

CSF density has an impact on the spread of local anaesthetic. Baricity of solution is based on normal CSF density.

## **COMPLICATIONS AND CONTRAINDICATIONS OF SUBARACHNOID BLOCK**

### **COMMON IMMEDIATE**

Hypotension.

Shivering

Temporary backache.

Itching (with opioids).

### **UNCOMMON IMMEDIATE**

Failure or inadequate blockade

Bradycardia secondary to blockade of sympathetic supply to heart.

Impairment of accessory muscles of respiration.

Horner's syndrome(Stellate ganglion involvement).

Phrenic nerve paralysis(C3,C4,C5)

### **UNCOMMON LATE**

Urinary retention.

Dural tap headache.

Neurological damage secondary to direct trauma and spinal cord ischemia.

Meningitis

Arachnoiditis

## **CONTRAINDICATIONS**

### **ABSOLUTE**

Patient refusal.

Local anesthetic allergy.

Technical difficulties.

Active local infection at the site of puncture.

### **RELATIVE**

Bleeding disorders.(e.g.INR>1.2 )

Hemophilia.

Continuing Anti coagulation.

Uncorrected hypovolemia.

Severe stenotic cardiac lesion.

Raised intra cranial pressure.

### ASRA Recommendations for Spinal/Epidural Anesthesia and Anticoagulants

<b>Classifications</b>	<b>Drugs</b>	<b>Recommendations</b>	<b>Investigations</b>
<b>Antiplatelets</b>	Aspirin/NSAIDS	None	None
	Ticlopidine	DC 14 days before	None
	Clopidogrel	DC 7 days before	None
	Abciximab	DC 2 days before	None
	Eptifibatide	DC 8 hours before	None
<b>Anticoagulants</b>	Warfarin	DC 4-5 days before Monitor patient for 24 hours post spinal, epidural or removal of catheter	PT/INR prior to needle placement or catheter removal; INR <1.5
<b>Heparin</b>	S.C heparin	Delay until after block	>4 days check plt count  Measure PTT
	IV heparin	Delay until 1 hour after block; remove catheter 2-4 hours after last dose.	
<b>LMWH</b>	Ardeparin Dalteparin Enoxaparin Tinzaparin Danaparoid	*Preop: block 10-12 hrs after last dose; high dose delay 24 hrs. (enoxaparin) *Postop: Twice daily dose delay 1st dose for 24 hrs; 2 hr delay after catheter removal. Once daily dose 1st dose 6-8 hrs post op; remove catheter 10-12 hr after last dose and wait 2 hrs till next dose. (enoxaparin)	None

<b>Herbal Preparations</b>	Garlic	DC 5-7 days before surgery	None
	Ginkgo		
	Ginseng		
	Ginger		
	Feverfew		
	Vitamin E		
<b>New Anticoagulants</b>	Bivalirudin	Unknown; assess risk Extreme caution; atraumatic needle placement; no catheters	None
	Lepirudin		
	Fondaparinux		

**CHOICE OF ANAESTHESIA  
FOR UROLOGICAL  
PROCEDURES**



# **CHOICE OF ANAESTHESIA FOR UROLOGICAL PROCEDURES**

Ideal anaesthesia should provide adequate operating conditions and analgesia. Physiological disturbance should be minimal and compensatory mechanism should not be compromised. Bleeding must be minimized. There should be adequate muscle relaxation and good surgical field.

The technique must allow early detection of overhydration, perforation and hemolysis.

Sub arachnoid block is the method of choice as:

- 1.Minimal anaesthesia is required.
- 2.Patient remains awake and mentation can be assessed regularly.
- 3.Respiration is minimally affected.
- 4.Early recognition of complications is possible(Level to be restricted to T<sub>10</sub>).
- 5.Peripheral vasodilatation helps to reduce circulatory overload.
- 6.Morbidity and mortality is low.

Regional anaesthesia however, does not abolish Obturator reflex (external rotation and adduction of thigh secondary to stimulation of obturator nerve by electrocautery current through lateral wall of bladder).

This reflex is reliably blocked either by muscle paralysis during general anaesthesia or Obturator nerve block.

General anaesthesia is usually given in major surgeries such as nephrectomy, cystectomy and renal transplantation.

**ANAESTHETIC IMPLICATIONS  
OF UROLOGICAL  
PROCEDURES**

# **ANAESTHETIC IMPLICATIONS OF UROLOGICAL PROCEDURES**

This study was done in Trans Urethral Resection of Prostate, Vesicolitholapaxy, Ureteroscopic stone lithotripsy and Optical Internal Urethrostomy.

## **URETEROSCOPIC STONE LITHOTRIPSY**

Here mid and lower ureteric stones are broken and it is removed through the ureteroscope. Simultaneously an irrigating solution 0.9% normal saline flows into the surgical site through the channel in the ureteroscope. Thus broken stones are washed out and clear surgical field is maintained.

## **TRANS URETHRAL RESECTION OF PROSTATE**

A resection of benign hypertrophic prostate tissue by a movable electrocautery cutting wire loop located at the end of urethroscope. Simultaneously 1.5 % glycine at a pressure of less than 70 cm of H<sub>2</sub>O is irrigated through the ureteroscope to distend the bladder. This helps to wash away blood and tissue debris.

## **VESICOLITHOLAPAXY**

Here bladder stones are broken and subsequently removed through a cystoscope. 0.9% normal saline is used as irrigating fluid here.

## **OPTICAL INTERNAL URETHROSTOMY.**

It is done for stricture urethra. Endoscopy provides a direct vision of stricture. A filiform is passed through the stricture and used as a guide during lysis. A catheter is left in place for a short time to prevent bleeding and pain. 0.9% normal saline is used as irrigating fluid.

## **INTRA OPERATIVE COMPLICATIONS.**

### **TURP SYNDROME.**

Trans Urethral Resection of Prostate often opens the extensive network of venous sinuses and potentially allows systemic absorption of irrigating fluid. The absorption of larger amount of fluids (>2 L) results in water intoxication, hyponatremia, hypoosmolality, cerebral edema, pulmonary edema, hemolysis, hypoxia and solute toxicity (hyperglycinemia and hyperammonemia).

### **Prevention.**

Irrigation fluid should be at a maximum height of 60 cm (2 feet) above the level of pubic symphysis. This creates hydrostatic pressure around 60 to 70 cm of H<sub>2</sub>O which is the maximum allowable limit.

## **Treatment**

Treatment depends on early recognition and severity of symptoms. Symptomatic hyponatremia ( $\text{Na}^+ < 120 \text{ mEq/lit}$ ) resulting in seizures or coma should be treated with hypertonic saline. Seizure activity terminated with low dose of midazolam (3-4 mg). Fluid restriction, loop diuretics, mannitol, ionotropic agents or even dialysis can be done appropriately. Endotracheal intubation is generally advised to prevent aspiration.

## **HYPOTHERMIA.**

Large volume of irrigating fluid at room temperature can be a major source of heat loss. In regional anaesthesia there is redistribution of body heat from deep to superficial tissue. In the area of block ability to shiver is lost and metabolic response to trauma is obtunded. This collectively causes hypothermia.

Hypothermia manifests as altered mental status, shallow respiratory pattern, cardiac rhythm disturbances (SVT, AF, Ventricular ectopics) and delayed recovery from anaesthesia. Hypothermia also leads to metabolic disturbances, reduced liver and renal perfusion and induce coagulopathy.

## **Treatment**

Mild hypothermia is corrected with gradual spontaneous rewarming with a blanket and warm IV fluids. But severe hypothermia needs active warming methods along with continuous core temperature monitoring.

## **OVER HYDRATION**

The syndrome of over hydration consist of triad of signs –bradycardia, elevated SBP and DBP with increased pulse pressure and cerebral agitation and depression .When over hydration is suspected, immediate measurement of serum Na<sup>+</sup> and serum osmolality should be done. When patient develops neurological symptoms prompt intervention is required.

## **BLADDER PERFORATION**

This can be due to instrumentation or over distension of bladder. Patients present with abdominal pain radiating to shoulder or suprapubic region, rigidity, nausea, vomiting ,diaphoresis, bradycardia, hypertension and shock like picture. Extra peritoneal rupture can be treated conservatively. Intra peritoneal rupture requires surgical repair.

## **BLOOD LOSS**

Visual estimation of blood loss is difficult due to dilution of blood with irrigating fluid. Warning signs like tachycardia and hypotension are masked by bradycardia and hypertension of over hydration syndrome.

The way to calculate true blood loss is to collect all of the irrigating-blood mixture and to measure its hemotocrit:

$$\text{Blood loss (ml)} = \frac{\text{Hb of irrigating fluid (gm/ml)} \times \text{Volume of irrigating fluid}}{\text{Patient's Hb (gm/lit)}}$$

Methods of quantifying blood loss are

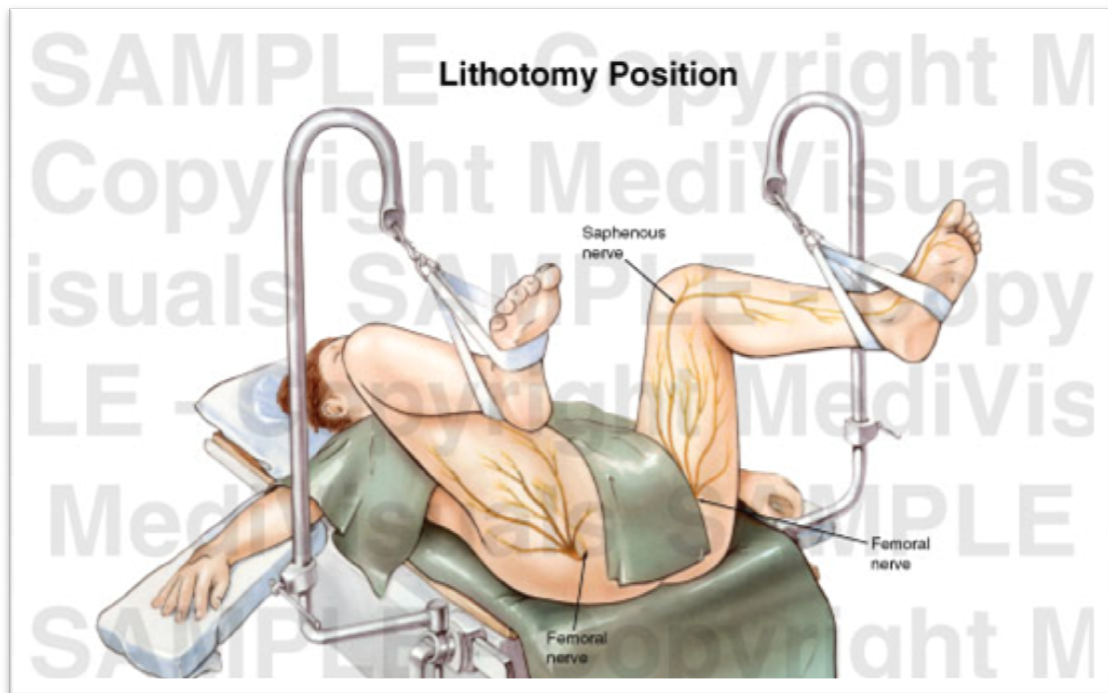
1. Radioactive labelling of RBC's
2. Alteration in electrical conductivity.
3. Calorimetric method.

## **LITHOTOMY POSITION**

Lithotomy position is the most commonly used position for endoscopic urological procedures.



Two persons are required to safely move the patients leg simultaneously up or down. Both the legs are elevated and flexed simultaneously and thighs are flexed about 90 degree to abdomen and outwardly rotated.



### **Complications of lithotomy position**

#### **Peripheral nerve injury**

Common peroneal nerve (L4,L5,S1,S2).-Injury to this nerve results in loss of dorsiflexion of foot and results in foot drop.

Obturator nerve(L2,L3,L4).-Acute flexion of the thigh to groin causes compression of this nerve and it leads to paralysis of adductors of thigh.

Saphenous nerve(L2,L3,L4).-Compression of medial aspect of the leg against the knee brace results in sensory loss to medial side of thigh.

Brachial plexus injury and compartment syndrome of lower extremity are also reported.

### **Cardiorespiratory compromise**

Functional residual capacity decreases and predisposes to atelectasis and hypoxia. Lithotomy position results in 18% reduction in vital capacity. Elevation of the legs increases venous return and it may exacerbate congestive cardiac failure. Rapid lowering of leg acutely decreases venous return and results in hypotension.

### **Venous stasis**

Stasis occurs at points of compression by equipments or at the groin due to thigh flexion. Patients with varicose veins are at high risk. Lithotomy position more than 15 mins have to be protected by elastic stockings.

**METHODS  
OF  
PAIN MEASUREMENT**

## **METHODS OF PAIN MEASUREMENT**

Pain is defined by International association as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in the terms of such damage”.

Methods of pain measurement includes

1. Visual analogue pain scale.
2. Verbal rating scale.
3. Mc Gill pain Questionnaire.
4. The Descriptor Differential scale.

### **VISUAL ANALOGUE PAIN SCALE ADVANTAGES**

1. Simple, efficient, minimally intrusive measure of pain intensity.
2. Widely used in clinical as well as research settings.
3. Provided that adequate clear instructions are given to the patient, its conceptual simplicity.

### **DISADVANTAGES**

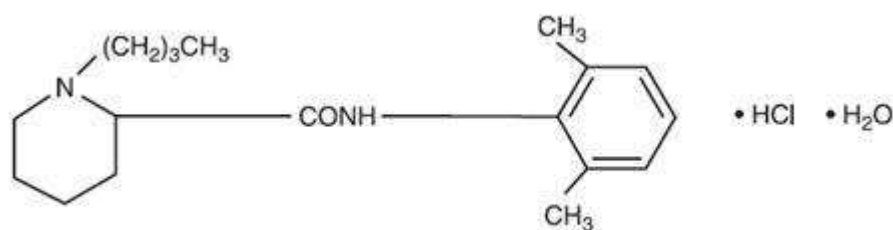
1. Bias of expectancy for change and reliance on memory.
2. It is assumed that pain is a unidimensional experience.

**PHARMACOLOGY  
OF  
BUPIVACAINE**

## PHARMACOLOGY OF BUPIVACAINE

Bupivacaine (MARCAINE, SENSORCAINE), is a widely used amide local anesthetic; its structure is similar to that of lidocaine except that the amine-containing group is a butyl piperidine

Bupivacaine is an amino amide local anaesthetic with a slow onset. It is long acting and suitable for procedures lasting 2 – 2.5 hrs. It was first synthesized by Ekenstam in 1957 and was used clinically in 1963.



It is available as hyperbaric solution in concentrations of 0.5% and 0.75% with dextrose 8.25%. Available Isobaric solutions are in concentrations of 0.5% and 0.75%. Maximum dose is 2mg/kg body weight.

## PHYSICO-CHEMICAL PROFILE.

Molecular weight(base)	288
pKa	8.16
Solubility in	
Alcohol	1 in 8
Water	1 in 25
Octanol/water partition coefficient	High
Lipid solubility	28
Plasma protein binding	95%
Anaesthetic index	3.0-4.0

## MECHANISM OF ACTION

Local anesthetics cause reversible blockade of impulse conduction along nerve axons and other excitable membranes. This action is by direct interaction of drug with voltage gated Na<sup>+</sup> channels. This can be used clinically to block pain sensation from - or sympathetic vasoconstrictor impulses to - specific areas of the body. Bupivacaine also reduces the permeability of the resting nerve membrane to potassium as well as sodium ions.

## **PHARMACODYNAMICS**

Bupivacaine by virtue of its pharmacological effects, has a stabilizing action on all excitable membranes. In the central nervous system, stimulation can occur producing restlessness, tremors and convulsions in over dosage. Bupivacaine can also causes a reduction of automaticity in the heart.

## **PHARMACOKINETICS**

### **ABSORPTION**

The absorption depends on:

1. Site of injection(intercostals>caudal>epidural>brachial plexus > subcutaneous)
2. Dose- the peak blood concentration increases with increase in dose.
3. Presence of vasoconstrictors-delays absorption.

### **DISTRIBUTION**

Bupivacaine is 95% protein bound to albumin and alpha-1 acid glycoprotein.

### **METABOLISM**

Occurs in liver by N-dealkylation, primarily to pipecolylxylidine. N-desbutyl bupivacaine and 4-hydroxy bipivacaine are the other metabolites produced.



## **EXCRETION**

Excretion is through urine(5% as pipecolylxylidine and 16% as unchanged form).The clearance is 0.47 l/min and elimination half life is 162 mins.

## **EFFECTS IN CVS**

It has marked cardiotoxic properties. It can bind to myocardial proteins and thus decreases the rate of increase of phase 0 during the cardiac action potential. In higher concentration, the peripheral vascular resistance and myocardial contractility are reduced and this can lead to cardiovascular collapse.

## **EFFECTS IN CNS**

In CNS it causes reversible neural blockade. It has characteristic biphasic effect in CNS. Intial excitation is caused by inhibition of inhibitory interneuron pathways in cortex. In higher doses both facilitatory and inhibitory pathways are depressed.

## **ADVERSE REACTIONS**

### **CNS**

Excitation characterized by restlessness, anxiety, dizziness, tinnitus, blurred vision or tremors proceeding to convulsions, followed by drowsiness, unconsciousness and cardiac arrest.

## **CVS**

Cardiotoxicity effects are due to high lipid solubility and high protein binding properties of the drug. Accidental intravenous injection causes dysrhythmias, atrioventricular block, ventricular tachycardia and ventricular fibrillation.

## **ALLERGY**

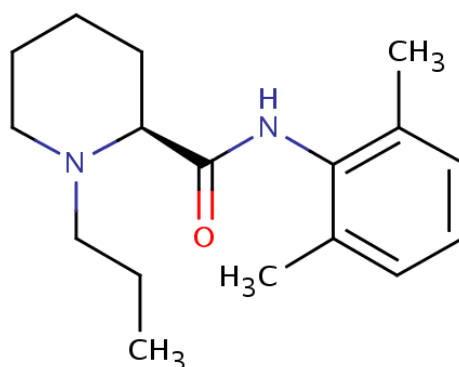
Allergy is extremely rare. It manifests as urticaria, pruritis, angioneurotic edema etc.

**PHARMACOLOGY  
OF  
ROPIVACAINE**

## PHARMACOLOGY OF ROPIVACAINE

Ropivacaine is a member of amino amide class of local anaesthetic. The amino ethylamide ropivacaine is the *S*-enantiomer of 1-propyl-2', 6'-pipecoloxylidide. Ropivacaine is structurally similar to Bupivacaine and Mepivacaine.

### STRUCTURE



### MECHANISM OF ACTION

Local anesthetics block conduction by decreasing or preventing the large transient increase in the permeability of excitable membranes to  $\text{Na}^+$  that normally is produced by a slight depolarization of the membrane (Strichartz and Ritchie, 1987). This action of local anesthetics is due to their direct interaction with voltage-gated  $\text{Na}^+$  channels. As the anesthetic action progressively develops in a nerve, the threshold for electrical excitability

gradually increases, the rate of rise of the action potential declines, impulse conduction slows, and the safety factor for conduction decreases. These factors decrease the probability of propagation of the action potential, and nerve

## **PHARMACOKINETICS**

Molecular weight	328.89
pKa	8.1
t <sub>1/2</sub>	111
Clearance	0.7 l /min
Protein binding	94%
Lipid solubility	Intermediate

## **ABSORPTION**

Absorption is similar to Bupivacaine.

## **DISTRIBUTION**

Protein bounding in plasma is about 94% predominantly to alpha 1 acid glycoprotein; the volume of distribution is 52-66 l.

## **METABOLISM**

By aromatic hydroxylation Ropivacaine is metabolized in liver through cytochrome CYP1A2 to the major metabolite 3-hydroxy-ropivacaine. 4-hydroxy-ropivacaine and 4-hydroxy-dealkylated-ropivacaine are also produced.

## **EXCRETION**

The clearance is 0.44-0.82 l/min. The elimination half life is 59-173 mins. 86% of dose is excreted in urine, 1% unchanged.

## **EFFECTS IN CVS**

Ropivacaine is less cardiotoxic than Bupivacaine. It has biphasic vascular effect, causing vasoconstriction at low but not at high concentrations. In higher concentrations, the peripheral vascular resistance and myocardial contractility are decreased.

## **EFFECTS IN CNS**

It causes reversible neural blockade. Has similar biphasic effects as Bupivacaine.

Maximum dose is 3mg/kg body weight.

## **ADVERSE REACTIONS.**

Allergy to amide linked local anaesthetics are extremely rare. Bronchospasm, urticaria and angioneurotic edema may occur.

Treatment of allergic reactions is with oxygen, injection of epinephrine and hydrocortisone.

**PHARMACOLOGY**  
**OF**  
**FENTANYL**

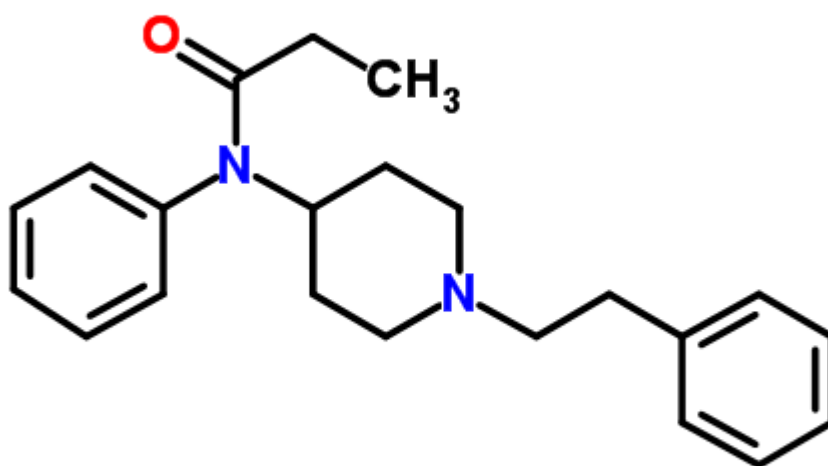


## PHARMACOLOGY OF FENTANYL

A tertiary amine which is a synthetic phenylpiperidine derivative.<sup>4</sup>  
anilinopiperidines that are structurally related to pethidines,

It act at  $\mu$  receptors as a agonist. It is more specific, shorter acting and  
80-100 times more potent than Morphine.

### STRUCTURE



## **PREPARATION**

It is available as a clear solution for injection containing 50 micrograms/ml Fentanyl citrate.

## **ROUTE OF ADMINISTRATION.**

Oral, parenteral (iv, im), neuraxial (subarachnoid and epidural), trans mucosal, transdermal.

## **MECHANISM OF ACTION**

It is a highly selective mu-agonist which specifically appears to be involved in the mediation of analgesia. Opioids appear to exert their effects by interacting with pre-synaptic G<sub>i</sub>-protein receptors.

## **PHARMACOLOGY OF SPINAL FENTANYL**

Dose	5-25 µg
Onset	5-15 mins
Duration	2-4 hrs.

## PHARMACOKINETICS

### METABOLISM

Fentanyl is extensively metabolized by N-demethylation producing Norfentanyl, which is structurally similar to Normeperidine. It is excreted by the kidneys.

pKa	8.4
Molecular weight	286
Bound to plasma protein	84%
T <sub>1/2</sub> $\mu$	1-2 mins
T <sub>1/2</sub> $\alpha$	10-30 mins
T <sub>1/2</sub> $\beta$	2-4 hrs
Clearance	10-20ml/kg/min
Hepatic extraction ratio	0.8-0.1.
Octanol-water partition coefficient	817

## **CLINICAL PROPERTIES**

Minimal CSF spread.

Rapid onset.

Short duration.

Low CSF solubility.

Decreased side effects.

Rapid analgesia.

## **EFFECTS IN CVS:**

Most significant effect is bradycardia caused by vagal stimulation. It does not affect cardiac output, mean arterial pressure, pulmonary capillary wedge pressure, pulmonary and systemic vascular resistance.

## **EFFECTS IN RS:**

Potent respiratory depressant. It decreases both respiratory rate and tidal volume. It also diminishes ventilator response to hypoxia and hypercapnia. Chest wall rigidity (wooden chest phenomenon) may occur.

## **EFFECTS IN CNS**

Analgesia, euphoria, sedation, hypnosis, miosis, nausea and vomiting.

## **EFFECTS IN GI TRACT**

Delays gastric emptying, biliary colic.

**ENDOCRINE :** Attenuation of stress response.

## **ADVERSE EFFECTS**

Pruritis, sedation, nausea, vomiting, apnea, urinary retention, seizures and chest wall rigidity may occur.

# **REVIEW OF LITERATURE**

## **REVIEW OF LITERATURE**

**1. Randomized double-blind comparison of ropivacaine-fentanyl and bupivacaine-fentanyl for spinal anaesthesia for urological surgery. Acta Anaesthesiol Scand. 2005 Nov;49(10):1477-82.**

Lee YY, conducted a prospective randomized double-blind study among 34, ASA 1-3 patients; planned for urological surgery with combined spinal epidural technique. He administered 10 mg of plain ropivacaine with 15 µg of fentanyl and 10 mg of plain bupivacaine with 15 µg of fentanyl two groups. And with his observation he concluded that sensory block upto T10 and motor blockade was attained in both groups in almost similar time. The duration of motor blockade was shorter in ropivacaine group with median of 126 mins and  $P=0.003$ . Hemodynamic changes did not show significant difference between these groups.

**2. Spinal anaesthesia: comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. Acta Anaesthesiol Belg. 2008;59(2):65-71**

Mantouvalou, performed a randomized control study with 120 patients (ASA 1-3) of 3 groups (40 each), to compare the effects of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. Group A, B and C received 15 mg of isobaric bupivacaine, ropivacaine and

levobupivacaine respectively. The onset and duration of sensory block upto T8, maximum spread of sensory block, onset, intensity and duration of motor block and any adverse effects were observed and recorded. Patients receiving bupivacaine showed faster onset of motor block than ropivacaine but almost the same as of levobupivacaine ( $P<0.05$ ). Ropivacaine provided shorter duration of both motor and sensory block than other two drugs ( $P<0.05$ ). Bupivacaine group experienced more side effects like hypotension and bradycardia.

**3. Comparison of ropivacaine and bupivacaine for intrathecal anesthesia during outpatient arthroscopic surgery. J Clin Anesth. 2006 Nov;18(7):521-5.**

Boztuğ N conducted randomized single blinded study with 90 patients scheduled for outpatient arthroscopic knee surgery. The patients were randomly divided into Group R (15 mg isobaric ropivacaine) and Group B (7.5 mg isobaric bupivacaine). The drugs were administered with patient in lateral recumbent position at L3-L4 space with 27 G Quinke spinal needle. The study showed that the onset time of sensory block upto L1 was shorter in Group R. Complete motor block was observed in 40 patients with ropivacaine and in 45 patients with bupivacaine. First ambulation, first urination and discharge time were similar in both groups. Ropivacaine provides higher cephalad spread of sensory block ( $P<0.05$ ).



**4.Comparison of intrathecal isobaric bupivacaine-morphine and ropivacaine-morphine for Caesarean delivery. Br J Anaesth. 2003 May;90(5):659-64**

Oğün CO : This study included 50 healthy parturients undergoing Caesarean delivery. Twenty five patients in Group RM received intrathecal 15 mg ropivacaine and 150 microgram morphine and twenty five patients in Group BM received 15 mg bupivacaine and 150 microgram morphine. Sensory and motor blockade, haemodynamics, postoperative pain relief, fetal outcomes and parameters, and side-effects were observed.

Complete motor block was attained in a shorter time in BM group than the RM group ( $P<0.05$ ). The time for the block to drop to the S2 dermatome were similar in both groups ( $P>0.05$ ). Time of first perception of pain and the need for consumption of tenoxicam were similar in both groups ( $P>0.05$ ). Fetal outcome was observed in terms of APGAR scores at 1 and 5 min and were similar in both groups ( $P>0.05$ ). The most common side effects observed were hypotension and pruritis.

**5.Comparison of the effects of intrathecal ropivacaine, levobupivacaine, and bupivacaine for Caesarean section. Br J Anaesth. 2003 Nov;91(5):684-9.**

Gautier P conducted a study to compare the effects of ropivacaine, levobupivacaine and bupivacaine by combined spinal-epidural technique in caesarean section. Ninety parturients were selected and they randomly received isobaric bupivacaine 8 mg, levobupivacaine 8 mg or ropivacaine 12 mg, Sufentanyl 2.5 micro gram was added as a common additive. Effectiveness of the drug was assessed on the basis of providing adequate sensory block upto T4 and requirement of intraoperative epidural top-ups. The study showed that effective anaesthesia was attained in 97,80 and 87 % of parturients in bupivacaine, levobupivacaine and ropivacaine groups respectively.( $P<0.05$ ).Bupivacaine also provided longer duration of sensory and motor blockade( $P<0.05\%$ ).

**6.Intrathecal sufentanil or fentanyl as adjuvants to low dose bupivacaine in endoscopic urological procedures.**

Gupta SSampley conducted a prospective,randomized,double-blinded study to compare the effects of sufentanil and fentanyl as additive to low dose bupivacaine in spinal anaesthesia in endoscopic urological procedures.A 90 patients (40-80 years) were selected and grouped as A ,B and C.Group A ,B

and C are provided with intrathecal 0.5% of 7.5 mg hyperbaric bupivacaine, or the same by adding sufentanil 10µg and fentanyl 25 µg respectively. Quality of anaesthesia and analgesia are observed. Maximum level of attainment of sensory block was higher in Group A. Sufentanyl provided better and prolonged analgesia. But motor block intensity and duration was better with Group A.

## **7.Neuraxial anesthesia versus general anesthesia for urological surgery: systematic review.**

Barbosa FT This study was conducted in an idea to choose best anaesthetic technique for urological surgeries. Neuraxial blockade and general anaesthesia were compared. They collected 2720 study datas from the Cochrane Central Register of Controlled Trials in the Cochrane Library (Issue 10, 2012), Medline via PubMed (1966 to October 2012), Lilacs (1982 to October 2012), SciELO and EMBASE (1974 to October 2012) and were analysed.. Randomized controlled trials (RCT) studies were included.. Among these studies 11 fulfilled the inclusion criteria. The study validity was: Jadad score >= 3 in one RCT; seven RCTs with unclear risk of bias as the most common response; and five RCTs not fulfilling half of the Delphi list items. The frequency of mortality was not significant between study groups in three RCTs. Meta-analysis was not performed. And they concluded

that the evidence available cannot prove that neuraxial anesthesia is more effective and safer than general anesthesia for urological surgery.

## **8.Comparison of equipotent doses of ropivacaine-fentanyl and bupivacaine-fentanyl in spinal anaesthesia for lower abdominal surgery.**

Koltka K A randomized double blinded study to compare the effects of plain ropivacaine and bupivacaine with fentanyl intrathecally for lower abdominal surgeries. 52 ASA I to II male patients posted for lower abdominal surgery were randomly assigned to receive plain ropivacaine 19.5 mg with fentanyl 20µg (group R, n =26) or plain bupivacaine 13 mg with fentanyl 20 µg (group B, n =26) intrathecally. The level and intensity of sensory block, level and duration of motor block, time to ambulate and patient satisfaction about pain relief were observed and recorded. Both groups achieved sensory block upto T10 or higher. Bupivacaine provided significantly higher sensory block (T4 [T3 to T7] vs T7 [T4 to T9],  $P < 0.05$ ). Ropivacaine provided shorter duration of motor block (Bromage score  $> 0$ ) (139+/-39 minutes vs group B 182+/-46 minutes,  $P < 0.05$ ). The duration and intensity of complete motor block (Bromage score=3) were also shorter in group R (90+/-25 minutes vs 130+/-40 minutes,  $P < 0.05$ ). And they concluded that intrathecal plain ropivacaine 19.5 mg plus fentanyl 20 µg provided a lower level of sensory block and a shorter duration of motor block than bupivacaine 13 mg plus fentanyl 20µg in lower abdominal surgery.

## **9. Intrathecal 0.75% Isobaric Ropivacaine Versus 0.5% Heavy Bupivacaine for Elective Cesarean Delivery: A Randomized Controlled Trial**

**Surjeet Singh**

This randomized control trial was done to compare the intrathecal efficacy and safety of 0.75% isobaric ropivacaine with 0.5% heavy bupivacaine in patients undergoing Caesarean delivery. They selected 46 parturients of ASA grade I-II planned for elective cesarean delivery. The parturients were randomized to receive either intrathecal 12.5 mg of 0.5% hyperbaric bupivacaine or 24 mg of 0.75% plain ropivacaine. Intraoperative vital parameters, intensity of sensory and motor nerve blockade, neonatal outcome and maternal adverse effect such as hypotension, bradycardia, nausea, vomiting, shivering or pruritis were observed and evaluated. Baseline variables were similar in the 2 groups ( $p$ -value  $> 0.05$ ). The time to achieve adequate sensory block to T10 ( $3.2 \pm 1.5$  vs  $2.5 \pm 1.3$  minutes) or to the maximal level ( $9.8 \pm 3.1$  vs  $7.9 \pm 2.3$  minutes) was longer in the ropivacaine group ( $p$ -value 0.048) but the median maximal level of sensory block was similar between the two groups ( $p$ -value  $> 0.05$ ). Ropivacaine gives shorter duration of sensory block ( $160.5 \pm 22.2$  vs  $182.3 \pm 30.5$  minutes) ( $p$ -value 0.03). Duration of motor block was also comparatively shorter in ropivacaine group ( $112.5 \pm 45$  vs  $165.3 \pm 26$ ) ( $p$ -value 0.004). Neonatal outcome was similar in both groups. They concluded that isobaric ropivacaine can be used as an effective and safe alternative to bupivacaine.

# **MATERIALS AND METHODS**

## **MATERIALS AND METHODS**

This is a prospective randomized control study. This study was conducted at the Institute of Urology in Rajiv Gandhi Government General Hospital between August 2014 and September 2014. This study was done in 100 patients presenting for elective endoscopic urological procedures of ASA physical status 1 and 2. Ethical committee approval and informed written consent from patients involved in this study are obtained before starting this study.

### **INCLUSION CRITERIA.**

Age	:	>18 years
Weight	:	Body Mass Index <30kg/m <sup>2</sup>
ASA	:	1 and 2.
Surgery	:	Elective
Mallampatti scores	:	I and II

Who have given valid informed written consent.

### **EXCLUSION CRITERIA.**

Not satisfying inclusion criteria

Patient posted for emergency surgery

Patients with difficult airway

Lack of informed written consent

Pregnant female

H/O any seizures and any neurological deficit

Severe renal, hepatic, respiratory and cardiovascular disease

Severe coagulopathy

Allergy to local anaesthetics

## **STUDY DESIGN**

Prospective randomized control study, single blinded.

## **STUDY POPULATION.**

100 Patients.

## **GROUP 1**

Patients in this group received intrathecal 11.25 mg (2.25ml) of 0.5% isobaric Bupivacaine and 12.5 µg (0.25 ml) of Fentanyl at L2-L3 intervertebral space in sitting position.



## **GROUP 2**

Patients in this group received intrathecal 11.25 mg (2.25 ml) of 0.5% isobaric Ropivacaine and 12.5 µg (0.25 ml) of Fentanyl at L2-L3 intervertebral space in sitting position.

## **MATERIALS**

25 gauge Quincke spinal needle.

Drugs: 0.5% Isobaric Bupivacaine and 0.5% Isobaric Ropivacaine(Ropin 0.5 in 10 ml ampoule).

Inj. Fentanyl 50 µg/ml, 2ml ampoule

Emergency drugs and crystalloids.

Monitors:ECG, NIBP, SPO<sub>2</sub>, PR.

## **PRE ANAESTHETIC EVALUATION.**

Patients included in this study underwent pre anaesthetic evaluation which included the following

## **HISTORY**

History of underlying comorbid illnesses like diabetes, hypertension, bronchial asthma, renal failure and seizures.

Previous history of surgery and any anaesthesia exposure noted.

History of any allergy to drugs noted.

## **PHYSICAL EXAMINATION**

General examination with regard to consciousness, orientation, head to toe examination and vital signs are assessed.

Height and weight noted.

Systemic examination of Cardiovascular system, respiratory system, central nervous system and abdominal examination done.

Local examination of spine and airway assessment done.

## **INVESTIGATIONS**

Complete hemogram (Hb%, RBC count, WBC count, Differential count, Platelet count)

Random blood sugar, Blood urea, Serum creatinine.

Serum electrolytes

Bleeding time, Clotting time

Urine albumin, sugar.

ECG, Chest Xray

Echo(if necessary).

Patients who satisfied the inclusion criteria are explained about the nature of study and anaesthetic technique and informed written consent was obtained.

### **PRE ANAESTHETIC PREPARATION.**

1. Anaesthetic machine is checked before starting the procedure.
2. Ensure the availability of working laryngoscope and endotracheal tubes of various sizes.
3. Make sure that the essential emergency drugs are available.
4. Ensuring the operating table tilts are corrected.
5. Obtain intravenous access (18 G cannula) and preload with 500 ml of crystalloid (Normal saline).
6. Connect monitors to the patient. (ECG, PR, NIBP, SPO<sub>2</sub>, RR) and base line vitals are observed.

### **TECHNIQUE**

Under strict aseptic precaution, patient in sitting position with flexion of spine and neck, lumbar region is painted and draped. L2-L3 intervertebral space is identified by using Tuffier's line. Then skin is infiltrated with 2 ml of 2% lignocaine. By midline approach 25 G Quincke's needle is inserted into subarachnoid space. After confirming free flow of clear CSF, 11.25 mg of

0.5% isobaric Bupivacaine / Ropivacaine with 12.5 microgram Fentanyl is injected.

## **OBSERVATION**

### **VITAL SIGNS**

Patient's pulse rate, SBP, DBP, MAP, SpO<sub>2</sub> and respiratory rate are observed at 1, 3, 5, 10, 15, 30, 45, 90 and 120 mins after subarachnoid blockade.

Common side effects observed after sub arachnoid block are hypotension and bradycardia. Hypotension is defined as a drop of systolic blood pressure of more than 20% from baseline (or) systolic BP of less than 90 mm of hg. It is managed with Inj. Ephedrine intravenously in increments of 6 mg as necessary.

Bradycardia is defined as heartrate of <60/min and it is managed with Inj. Atropine 0.6 mg .

Respiratory depression is defined as a respiratory rate <8/min (or) oxygen saturation of <85% and it is managed with bag and mask ventilation or endotracheal intubation and IPPV if warranted.

### **SENSORY BLOCK.**

1. Time of onset ( Time taken to attain T10 dermatomal level).
2. Duration of block. (Time of complete resolution of block).

## **MOTOR BLOCK.**

### **1. Onset of motor block.**

Degree of motor block is assessed by modified Bromage scale at 5 mins interval.

0 =able to raise straight leg against resistance i.e. no detectable motor block.

1=unable to raise straight leg but able to flex knee.

2=unable to flex knee but able to flex ankles.

3= unable to move hip, knee or ankle.

### **2. Duration of motor block.**

## **POST OPERATIVE VAS SCORE.**

Quality of analgesia is assessed by post operative visual analogue scale. It is observed hourly at 1,2,3,4,5,6 hrs in post operative room. The VAS is a 10 cm horizontal scale marked with “no pain” at one end and “worst pain” at other end. The patient is asked to mark on this line according to the intensity of pain they feel.

# RESULTS

## **RESULTS**

This study was conducted in Institute of Urology, Rajiv Gandhi Govt. General Hospital, Chennai during August 2014 and September 2014.

This study was conducted in elective endoscopic urological procedures URSL, VL, TURP and OIU. The patients were randomized into two groups- Group 1 and Group 2. The trial numbers are 50 in each group.

Group 1- Isobaric Bupivacaine with Fentanyl.

Group 2 –Isobaric Ropivacaine with Fentanyl.

The following results are obtained from this study:

### **AGE AND BMI DISTRIBUTION**

Age and BMI distribution in both groups are shown in the table below. The values are similar in both groups. The Student T-test done on the values revealed no statistical significance.

## T-Test

**Table 1**

**Group Statistics**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
AGE	GROUP 1	50	46.30	14.535	2.056
	GROUP 2	50	44.48	13.673	1.934
BMI	GROUP 1	50	23.23	1.620	.229
	GROUP 2	50	23.78	1.480	.209

**Table 2**

**Independent Samples Test**

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
AGE	Equal variances assumed	.331	.566	.645	98	.520	1.820	2.822	-3.780	7.420
	Equal variances not assumed			.645	97.636	.521	1.820	2.822	-3.781	7.421
BMI	Equal variances assumed	.992	.322	-1.766	98	.081	-.548	.310	-1.164	.068
	Equal variances not assumed			-1.766	97.220	.081	-.548	.310	-1.164	.068

P-value for age=0.520-Not significant.

P-value for BMI=0.081-Not significant.



## SEX DISTRIBUTION

### SEX GROUP

The sex distribution among the patients in two groups are analysed below.

**Table 3**

**Crosstab**

			GROUP		Total
			GROUP 1	GROUP 2	
SEX	MALE	Count	33	37	70
		% within GROUP	66.0%	74.0%	70.0%
	FEMALE	Count	17	13	30
		% within GROUP	34.0%	26.0%	30.0%
Total		Count	50	50	100
		% within GROUP	100.0%	100.0%	100.0%

**Table 4**

**Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.762 <sup>b</sup>	1	.383	.513	.257
Continuity Correction <sup>a</sup>	.429	1	.513		
Likelihood Ratio	.764	1	.382		
Fisher's Exact Test					
Linear-by-Linear Association	.754	1	.385		
N of Valid Cases	100				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 15.00.

P-value of Chi-Square test=0.513-Not significant.

## ASA GROUP

ASA 1 and 2 groups patients are only included in this study.

ASA 1-No systemic organic physiological, biochemical or psychiatric disturbance.

ASA 2-Mild to moderate systemic disturbances caused by the disease and has to be treated surgically or other pathophysiology (diabetic mellitus, mild hypertension, anemia, old age, obesity).

**Table 5**

**Crosstab**

			GROUP		Total
			GROUP 1	GROUP 2	
ASA I	Count		29	37	66
	% within GROUP		58.0%	74.0%	66.0%
	Count		21	13	34
	% within GROUP		42.0%	26.0%	34.0%
Total	Count		50	50	100
	% within GROUP		100.0%	100.0%	100.0%

**Table 6**

**Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.852 <sup>b</sup>	1	.091	.139	.069
Continuity Correction <sup>a</sup>	2.184	1	.139		
Likelihood Ratio	2.872	1	.090		
Fisher's Exact Test					
Linear-by-Linear Association	2.824	1	.093		
N of Valid Cases	100				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 17.00.

P value of Chi-Square test=0.139-Not significant.

## SURGERY GROUP

Patients undergoing various endoscopic urological surgeries are plotted and analysed below.

**Table 7**

**Crosstab**

			GROUP		Total
			GROUP 1	GROUP 2	
SURGERY	URS	Count	28	30	58
		% within GROUP	56.0%	60.0%	58.0%
	VL	Count	5	4	9
		% within GROUP	10.0%	8.0%	9.0%
	TURP	Count	10	12	22
		% within GROUP	20.0%	24.0%	22.0%
	OIU	Count	7	4	11
		% within GROUP	14.0%	8.0%	11.0%
Total		Count	50	50	100
		% within GROUP	100.0%	100.0%	100.0%

URSL-Ureteroscopic Stone Lithotripsy.

VL-Vesicolitholapaxy.

TURP-Trans Urethral Resection of Prostrate.

OIU-Optical Internal Urethrostomy.

**Table 8**

**Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.180 <sup>a</sup>	3	.758
Likelihood Ratio	1.191	3	.755
Linear-by-Linear Association	.292	1	.589
N of Valid Cases	100		

a. 2 cells (25.0%) have expected count less than 5. The minimum expected count is 4.50.

P-value of Chi-Square test=0.758-Not significant.

## **SENSORY BLOCK.**

Time taken for onset (upto T10 level) and duration of sensory block for patients in both groups are compared and subjected to Student T-test.

## **T-Test**

**Table 9**

**Group Statistics**

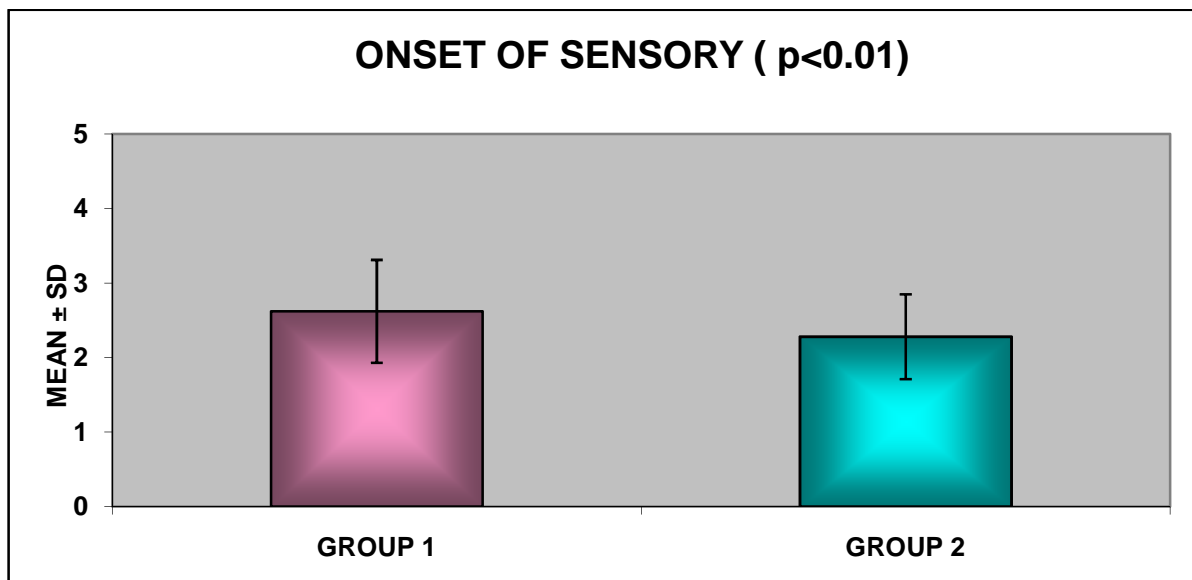
		N	Mean	Std. Deviation	Std. Error Mean
ONSET OF SENSORY	GROUP 1	50	2.62	.697	.099
	GROUP 2	50	2.28	.573	.081
DURATION OF SENSORY	GROUP 1	50	139.10	10.771	1.523
	GROUP 2	50	144.70	8.830	1.249

## T-Test

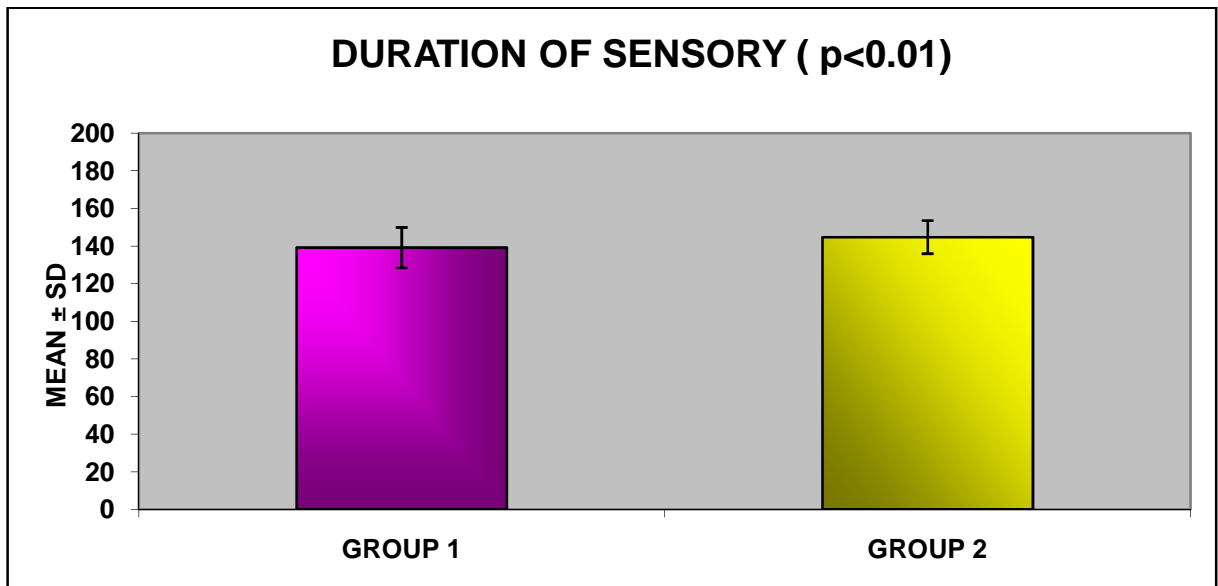
**Table 10**

Independent Samples Test									
		Levene's Test for Equality of Variances		t-test for Equality of Means					
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference
ONSET OF SENSORY	Equal variances assumed	7.408	.008	2.666	98	.009	.340	.128	.087 .593
	Equal variances not assumed			2.666	94.474				
DURATION OF SENSORY	Equal variances assumed	1.359	.247	-2.843	98	.005	-5.600	1.970	-9.509 -1.691
	Equal variances not assumed			-2.843	94.371				

GROUP1	GROUP2
2.62	2.28



Mean for onset of sensory block in group 1 is 2.62 and group 2 is 2.28; with mean difference 0.340 and  $P < 0.01$ . So time taken for sensory block upto T10 dermatomal level is earlier in ropivacaine group (Group 2).



GROUP1	GROUP2
139.1	144.7

Mean duration of sensory in group 1 is 139.10 and group 2 is 144.70 with mean difference -5.6 and  $P < 0.01$ . This shows duration of sensory block is comparatively longer in ropivacaine (Group 2) than bupivacaine (Group 1).

## MOTOR BLOCK

Time taken for onset and duration of motor block for patients in both groups are compared and subjected to student t test.

**Table 11**

**Group Statistics**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
ONSET OF MOTOR	GROUP 1	50	4.86	.881	.125
	GROUP 2	50	5.24	.716	.101
DURATION OF MOTOR	GROUP 1	50	140.50	11.260	1.592
	GROUP 2	50	98.30	7.257	1.026

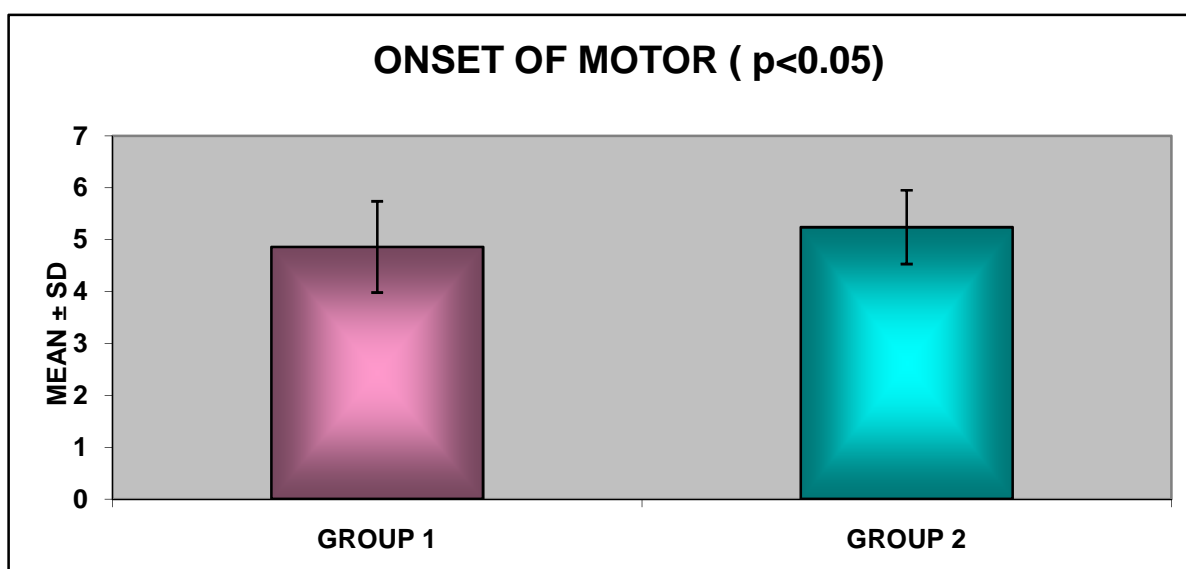
**Table 12**

**Independent Samples Test**

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
ONSET OF MOTOR	Equal variances assumed	2.427	.122	-2.367	98	.020	-.380	.161	-.699	-.061
	Equal variances not assumed			-2.367	94.073	.020	-.380	.161	-.699	-.061
DURATION OF MOTOR	Equal variances assumed	7.087	.009	22.275	98	.000	42.200	1.894	38.441	45.959
	Equal variances not assumed			22.275	83.717	.000	42.200	1.894	38.432	45.968

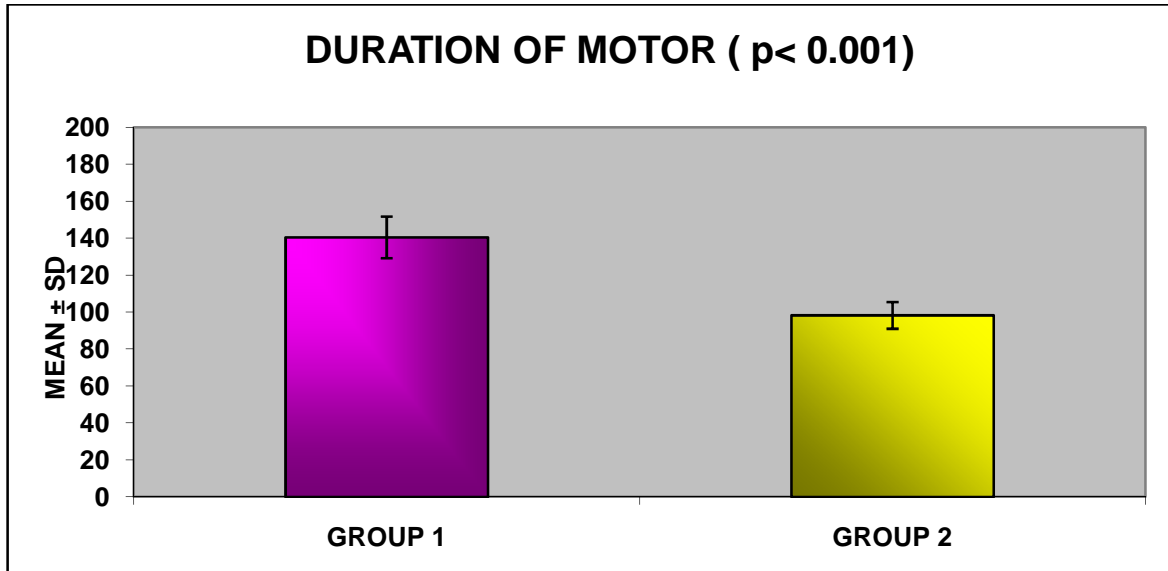
## ONSET OF MOTOR BLOCKADE

GROUP1	GROUP2
4.86	5.24



Mean value for onset of motor blockade in group 1(bupivacaine) is 4.86 and group 2 (ropivacaine) is 5.24;with mean difference -0.380 and  $P < 0.05$ . This shows onset of motor block is little earlier in bupivacaine group(Group 1).





GROUP1	GROUP2
140.5	98.3

Mean duration of motor blockade in group 1 is 140.50 and group 2 is 98.30 with mean difference 42.20 and  $P < 0.001$ . This shows longer duration of motor blockade is provided by bupivacaine (Group 1).

## T-Test

**Table 13**

**Group Statistics**

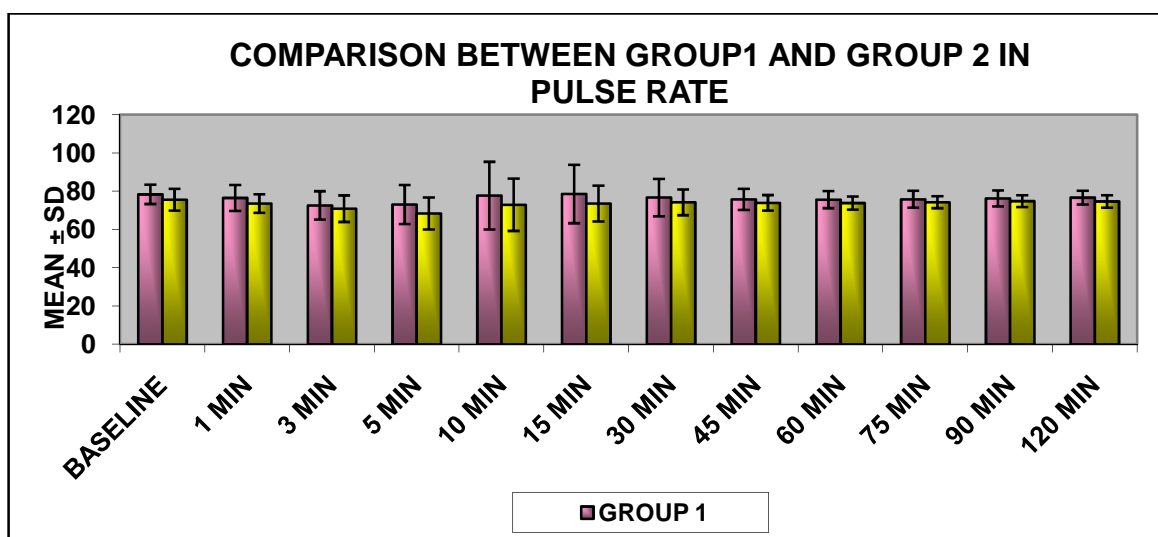
GROUP		N	Mean	Std. Deviation	Std. Error Mean
PR - BASELINE	GROUP 1	50	78.48	5.040	.713
	GROUP 2	50	75.72	5.686	.804
PR - 1 MIN	GROUP 1	50	76.62	6.758	.956
	GROUP 2	50	73.66	4.847	.685
PR - 3 MIN	GROUP 1	50	72.72	7.437	1.052
	GROUP 2	50	71.04	6.957	.984
PR - 5 MIN	GROUP 1	50	73.18	10.199	1.442
	GROUP 2	50	68.52	8.345	1.180
PR - 10 MIN	GROUP 1	50	77.88	17.689	2.502
	GROUP 2	50	73.06	13.682	1.935
PR - 15 MIN	GROUP 1	50	78.70	15.305	2.165
	GROUP 2	50	73.70	9.355	1.323
PR - 30 MIN	GROUP 1	50	76.84	9.805	1.387
	GROUP 2	50	74.32	6.738	.953
PR - 45 MIN	GROUP 1	50	75.84	5.538	.783
	GROUP 2	50	74.06	4.093	.579
PR - 60 MIN	GROUP 1	50	75.76	4.470	.632
	GROUP 2	50	73.94	3.461	.489
PR - 75 MIN	GROUP 1	50	75.92	4.444	.628
	GROUP 2	50	74.40	3.149	.445
PR - 90 MIN	GROUP 1	50	76.40	4.204	.595
	GROUP 2	50	74.94	3.133	.443
PR - 120 MIN	GROUP 1	50	76.82	3.607	.510
	GROUP 2	50	74.80	3.258	.461

## PULSE RATE

There was not much variation in pulse rate recordings between two groups.

## PULSE RATE

	<b>GROUP1</b>	<b>GROUP2</b>
<b>BASELINE</b>	78.48	75.72
1 MIN	76.62	73.66
3 MIN	72.72	71.04
5 MIN	73.18	68.52
10 MIN	77.88	73.06
15 MIN	78.7	73.7
30 MIN	76.84	74.32
45 MIN	75.84	74.06
60 MIN	75.76	73.94
75 MIN	75.92	74.4
90 MIN	76.4	74.94
120 MIN	76.82	74.8



P value for pulse rate at 1,3,5,10,15,30,45,60,75,90 and 120 mins lies between 0.05 and 0.1-this implies no statistical significance.

## T-Test

**Table 14**

**Group Statistics**

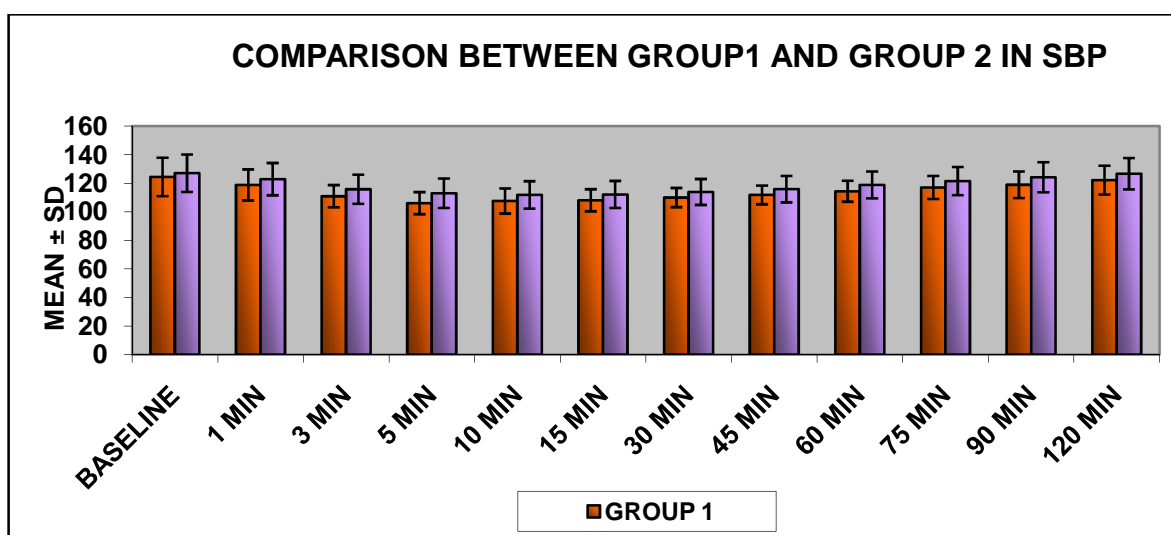
	GROUP	N	Mean	Std. Deviation	Std. Error Mean
SBP - BASELINE	GROUP 1	50	124.40	13.413	1.897
	GROUP 2	50	127.04	13.144	1.859
SBP - 1 MIN	GROUP 1	50	118.84	10.880	1.539
	GROUP 2	50	122.88	11.329	1.602
SBP - 3 MIN	GROUP 1	50	110.88	7.805	1.104
	GROUP 2	50	115.80	10.224	1.446
SBP - 5 MIN	GROUP 1	50	106.04	7.746	1.095
	GROUP 2	50	112.96	10.327	1.460
SBP - 10 MIN	GROUP 1	50	107.60	8.816	1.247
	GROUP 2	50	111.84	9.578	1.354
SBP - 15 MIN	GROUP 1	50	108.04	7.725	1.092
	GROUP 2	50	112.12	9.514	1.345
SBP - 30 MIN	GROUP 1	50	109.96	6.707	.948
	GROUP 2	50	113.92	9.080	1.284
SBP - 45 MIN	GROUP 1	50	111.84	6.563	.928
	GROUP 2	50	115.88	9.271	1.311
SBP - 60 MIN	GROUP 1	50	114.40	7.384	1.044
	GROUP 2	50	118.76	9.432	1.334
SBP - 75 MIN	GROUP 1	50	117.04	8.104	1.146
	GROUP 2	50	121.48	9.912	1.402
SBP - 90 MIN	GROUP 1	50	118.96	9.296	1.315
	GROUP 2	50	124.16	10.512	1.487
SBP - 120 MIN	GROUP 1	50	122.16	10.100	1.428
	GROUP 2	50	126.64	10.995	1.555

## SYSTOLIC BLOOD PRESSURE

Systolic blood pressures were normal (>100mmHg) in both groups and was not statistically significant.

## SYSTOLIC BLOOD PRESSURE

	GROUP1	GROUP2
<b>BASELINE</b>	124.4	127.04
1 MIN	118.84	122.88
3 MIN	110.88	115.8
5 MIN	106.04	112.96
10 MIN	107.6	111.84
15 MIN	108.04	112.12
30 MIN	109.96	113.92
45 MIN	111.84	115.88
60 MIN	114.4	118.76
75 MIN	117.04	121.48
90 MIN	118.96	124.16
120 MIN	122.16	126.64



P value for SBP at 1,3,5,10,15,30,45,60,75,90 and 120 mins lies between 0.05 and 0.1-this implies no statistical significance.

## T-Test

**Table 15**

**Group Statistics**

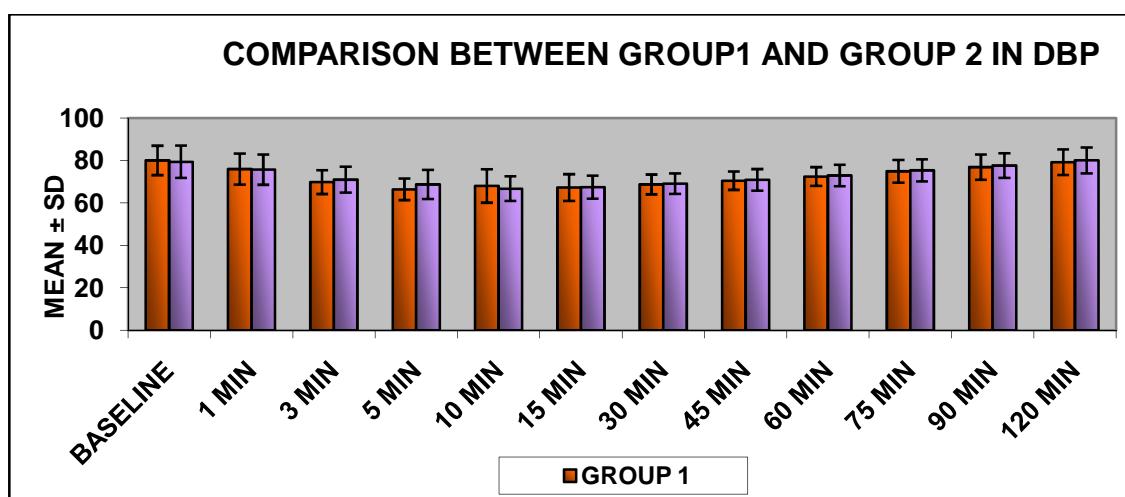
	GROUP	N	Mean	Std. Deviation	Std. Error Mean
DBP - BASELINE	GROUP 1	50	80.04	6.934	.981
	GROUP 2	50	79.40	7.626	1.079
DBP - 1 MIN	GROUP 1	50	75.96	7.279	1.029
	GROUP 2	50	75.72	7.149	1.011
DBP - 3 MIN	GROUP 1	50	69.80	5.617	.794
	GROUP 2	50	71.00	6.145	.869
DBP - 5 MIN	GROUP 1	50	66.40	5.079	.718
	GROUP 2	50	68.72	6.866	.971
DBP - 10 MIN	GROUP 1	50	68.00	7.887	1.115
	GROUP 2	50	66.72	5.824	.824
DBP - 15 MIN	GROUP 1	50	67.28	6.296	.890
	GROUP 2	50	67.48	5.433	.768
DBP - 30 MIN	GROUP 1	50	68.72	4.691	.663
	GROUP 2	50	69.12	4.835	.684
DBP - 45 MIN	GROUP 1	50	70.48	4.344	.614
	GROUP 2	50	70.88	5.098	.721
DBP - 60 MIN	GROUP 1	50	72.44	4.413	.624
	GROUP 2	50	72.92	5.082	.719
DBP - 75 MIN	GROUP 1	50	74.92	5.364	.759
	GROUP 2	50	75.36	5.228	.739
DBP - 90 MIN	GROUP 1	50	76.88	5.968	.844
	GROUP 2	50	77.64	5.795	.820
DBP - 120 MIN	GROUP 1	50	79.20	6.047	.855
	GROUP 2	50	80.08	6.114	.865

## DIASTOLIC BLOOD PRESSURE

The two groups had no significant difference in diastolic blood pressure.

## DIASTOLIC BLOOD PRESSURE

	GROUP1	GROUP2
<b>BASELINE</b>	80.04	79.4
1 MIN	75.96	75.72
3 MIN	69.8	71
5 MIN	66.4	68.72
10 MIN	68	66.72
15 MIN	67.28	67.48
30 MIN	68.72	69.12
45 MIN	70.48	70.88
60 MIN	72.44	72.92
75 MIN	74.92	75.36
90 MIN	76.88	77.64
120 MIN	79.2	80.08



P value for DBP at 1,3,5,10,15,30,45,60,75,90 and 120 mins lies between 0.05 and 0.1-this implies no statistical significance.

## MEAN ARTERIAL PRESSURE

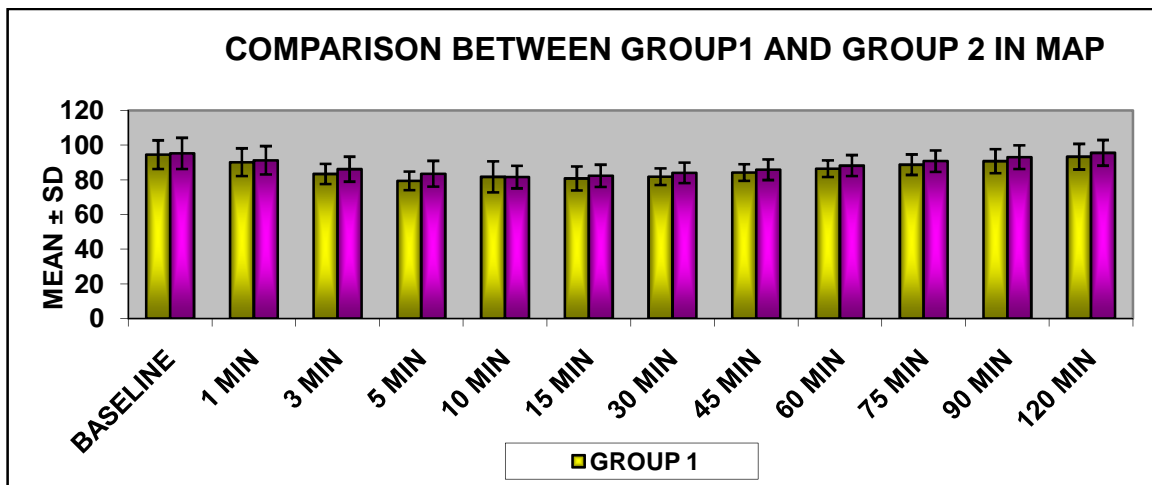
**Table 16**

**Group Statistics**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
MAP - BASELINE	GROUP 1	50	94.52	8.252	1.167
	GROUP 2	50	95.28	9.015	1.275
MAP - 1 MIN	GROUP 1	50	90.16	8.019	1.134
	GROUP 2	50	91.30	8.140	1.151
MAP - 3 MIN	GROUP 1	50	83.40	5.817	.823
	GROUP 2	50	86.16	7.218	1.021
MAP - 5 MIN	GROUP 1	50	79.44	5.372	.760
	GROUP 2	50	83.52	7.476	1.057
MAP - 10 MIN	GROUP 1	50	81.74	8.921	1.262
	GROUP 2	50	81.62	6.524	.923
MAP - 15 MIN	GROUP 1	50	80.82	6.889	.974
	GROUP 2	50	82.34	6.435	.910
MAP - 30 MIN	GROUP 1	50	81.84	4.761	.673
	GROUP 2	50	84.02	5.895	.834
MAP - 45 MIN	GROUP 1	50	84.26	4.793	.678
	GROUP 2	50	85.84	5.950	.841
MAP - 60 MIN	GROUP 1	50	86.42	4.803	.679
	GROUP 2	50	88.22	6.052	.856
MAP - 75 MIN	GROUP 1	50	88.76	5.920	.837
	GROUP 2	50	90.82	6.216	.879
MAP - 90 MIN	GROUP 1	50	90.76	6.915	.978
	GROUP 2	50	93.08	6.809	.963
MAP - 120 MIN	GROUP 1	50	93.36	7.392	1.045
	GROUP 2	50	95.60	7.373	1.043



	<b>GROUP I</b>	<b>GROUP II</b>
<b>BASELINE</b>	94.52	95.28
1 MIN	90.16	91.3
3 MIN	83.4	86.16
5 MIN	79.44	83.52
10 MIN	81.74	81.62
15 MIN	80.82	82.34
30 MIN	81.84	84.02
45 MIN	84.26	85.84
60 MIN	86.42	88.22
75 MIN	88.76	90.82
90 MIN	90.76	93.08
120 MIN	93.36	95.6



P value for MAP at 1,3,5,10,15,30,45,60,75,90 and 120 mins lies between 0.05 and 0.1-this implies no statistical significance.

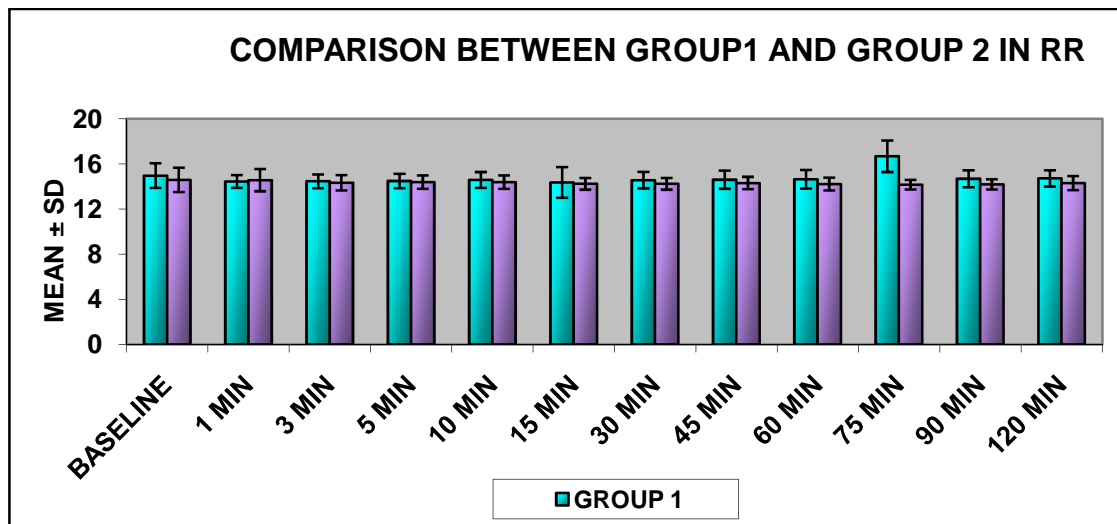
## RESPIRATORY RATE

**Table 17**

**Group Statistics**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
RR - BASELINE	GROUP 1	50	14.98	1.097	.155
	GROUP 2	50	14.60	1.088	.154
RR - 1 MIN	GROUP 1	50	14.46	.579	.082
	GROUP 2	50	14.58	.992	.140
RR - 3 MIN	GROUP 1	50	14.48	.614	.087
	GROUP 2	50	14.34	.688	.097
RR - 5 MIN	GROUP 1	50	14.50	.647	.091
	GROUP 2	50	14.40	.606	.086
RR - 10 MIN	GROUP 1	50	14.60	.700	.099
	GROUP 2	50	14.40	.606	.086
RR - 15 MIN	GROUP 1	50	14.38	1.369	.194
	GROUP 2	50	14.26	.527	.075
RR - 30 MIN	GROUP 1	50	14.58	.731	.103
	GROUP 2	50	14.26	.527	.075
RR - 45 MIN	GROUP 1	50	14.62	.805	.114
	GROUP 2	50	14.32	.551	.078
RR - 60 MIN	GROUP 1	50	14.66	.823	.116
	GROUP 2	50	14.42	.575	.081
RR - 75 MIN	GROUP 1	50	16.70	14.061	1.989
	GROUP 2	50	14.18	.438	.062
RR - 90 MIN	GROUP 1	50	14.70	.763	.108
	GROUP 2	50	14.20	.452	.064
RR - 120 MIN	GROUP 1	50	14.74	.723	.102
	GROUP 2	50	14.32	.621	.088

	<b>GROUP I</b>	<b>GROUP II</b>
<b>BASELINE</b>	14.98	14.6
1 MIN	14.46	14.58
3 MIN	14.48	14.34
5 MIN	14.5	14.4
10 MIN	14.6	14.4
15 MIN	14.38	14.26
30 MIN	14.58	14.26
45 MIN	14.62	14.32
60 MIN	14.66	14.24
75 MIN	16.7	14.18
90 MIN	14.7	14.2
120 MIN	14.74	14.32



P value for respiratory rate at 1,3,5,10,15,30,45,60,75,90 and 120 mins lies between 0.05 and 0.1-this implies no statistical significance.

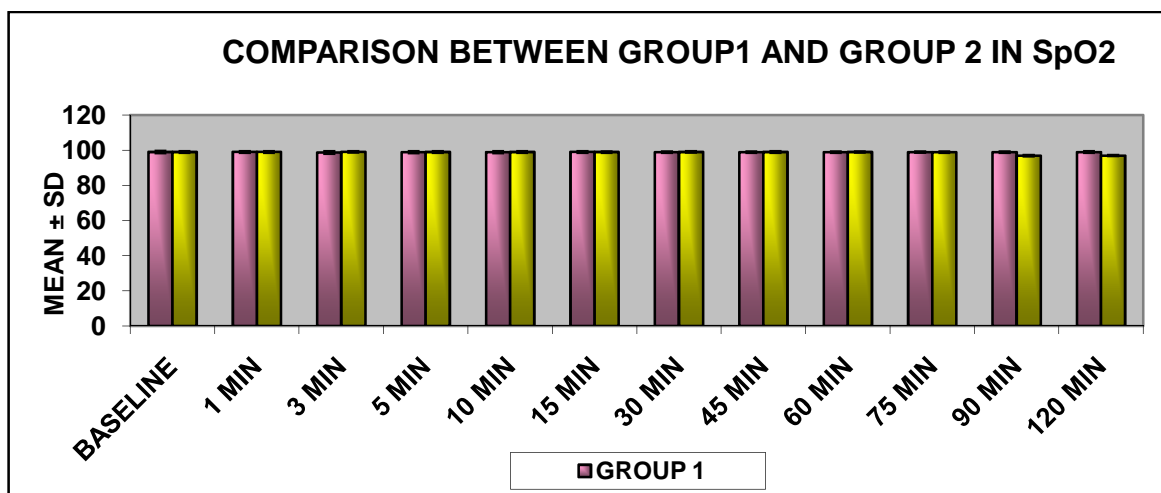
## OXYGEN SATURATION

**Table 18**

**Group Statistics**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
SpO2 - BASELINE	GROUP 1	50	98.98	.553	.078
	GROUP 2	50	99.00	.452	.064
SpO2 - 1 MIN	GROUP 1	50	99.02	.473	.067
	GROUP 2	50	99.04	.402	.057
SpO2 - 3 MIN	GROUP 1	50	98.68	.683	.097
	GROUP 2	50	99.02	.377	.053
SpO2 - 5 MIN	GROUP 1	50	98.88	.558	.079
	GROUP 2	50	98.98	.377	.053
SpO2 - 10 MIN	GROUP 1	50	98.94	.550	.078
	GROUP 2	50	98.96	.402	.057
SpO2 - 15 MIN	GROUP 1	50	99.02	.428	.061
	GROUP 2	50	98.96	.348	.049
SpO2 - 30 MIN	GROUP 1	50	98.84	.370	.052
	GROUP 2	50	99.00	.350	.049
SpO2 - 45 MIN	GROUP 1	50	98.92	.340	.048
	GROUP 2	50	98.98	.377	.053
SpO2 - 60 MIN	GROUP 1	50	98.86	.351	.050
	GROUP 2	50	98.96	.283	.040
SpO2 - 75 MIN	GROUP 1	50	98.92	.274	.039
	GROUP 2	50	98.96	.348	.049
SpO2 - 90 MIN	GROUP 1	50	98.90	.364	.052
	GROUP 2	50	99.02	.319	.045
SpO2 - 120 MIN	GROUP 1	50	98.94	.424	.060
	GROUP 2	50	99.00	.202	.029

SPO <sub>2</sub>	GROUP I	GROUP II
<b>BASELINE</b>	98.98	99
1 MIN	99.02	99.04
3 MIN	98.68	99.02
5 MIN	98.88	98.98
10 MIN	98.94	98.96
15 MIN	99.02	98.96
30 MIN	98.84	99
45 MIN	98.92	98.98
60 MIN	98.86	98.96
75 MIN	98.92	98.92
90 MIN	98.9	96.9
120 MIN	98.94	96.94



P value for SPO<sub>2</sub> at 1,3,5,10,15,30,45,60,75,90 and 120 mins lies between 0.05 and 0.1-this implies no statistical significance.

## QUALITY OF ANALGESIA

**Table 19**

**Group Statistics**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
VAS1	GROUP 1	50	.04	.198	.028
	GROUP 2	50	.02	.141	.020
VAS2	GROUP 1	50	.16	.370	.052
	GROUP 2	50	.04	.198	.028
VAS3	GROUP 1	50	1.06	.240	.034
	GROUP 2	50	.86	.452	.064
VAS4	GROUP 1	50	1.82	.482	.068
	GROUP 2	50	1.62	.490	.069
VAS5	GROUP 1	50	2.44	.611	.086
	GROUP 2	50	2.34	.479	.068
VAS6	GROUP 1	50	3.18	.941	.133
	GROUP 2	50	3.24	.591	.084

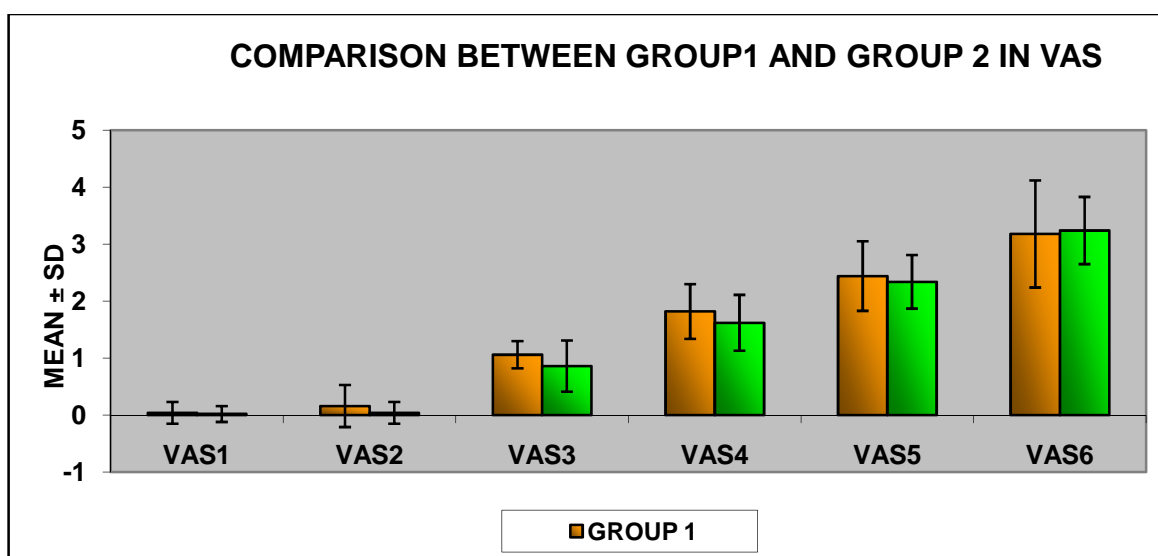
**Table 20**

**Independent Samples Test**

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
VAS1	Equal variances assumed	1.370	.245	.581	98	.562	.020	.034	-.048	.088
	Equal variances not assumed			.581	88.683	.563	.020	.034	-.048	.088
VAS2	Equal variances assumed	19.085	.000	2.021	98	.046	.120	.059	.002	.238
	Equal variances not assumed			2.021	74.887	.047	.120	.059	.002	.238
VAS3	Equal variances assumed	12.803	.001	2.763	98	.007	.200	.072	.056	.344
	Equal variances not assumed			2.763	74.557	.007	.200	.072	.056	.344
VAS4	Equal variances assumed	5.381	.022	2.057	98	.042	.200	.097	.007	.393
	Equal variances not assumed			2.057	97.971	.042	.200	.097	.007	.393
VAS5	Equal variances assumed	5.007	.028	.911	98	.365	.100	.110	-.118	.318
	Equal variances not assumed			.911	92.648	.365	.100	.110	-.118	.318
VAS6	Equal variances assumed	10.941	.001	-.382	98	.703	-.060	.157	-.372	.252
	Equal variances not assumed			-.382	82.464	.704	-.060	.157	-.373	.253

## POST OPERATIVE VISUAL ANALOGUE SCALE (1-6 HRS)

	GROUP1	GROUP2
VAS1	0.04	0.02
VAS2	0.16	0.04
VAS3	1.06	0.86
VAS4	1.82	1.62
VAS5	2.44	2.34
VAS6	3.18	3.24



P value of 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> hrs are <0.05.-Significant.

## SIDE EFFECTS

Side effects observed during this study are hypotension and bradycardia. Hypotension was managed with Inj. Ephedrine 6 or 12mg iv stat as necessary. Bradycardia was managed with Inj. Atropine 0.6 mg iv stat.

**Table 21**

**SIDE EFFECTS \* GROUP Crosstabulation**

			GROUP		Total
			GROUP 1	GROUP 2	
SIDE EFFECTS	Inj.Ephedrine 6	Count	3	1	4
		% within GROUP	6.0%	2.0%	4.0%
	Inj.Atrop 0.6	Count	4	2	6
		% within GROUP	8.0%	4.0%	6.0%
	Inj.Ephedrine 12	Count	2	1	3
		% within GROUP	4.0%	2.0%	3.0%
	Nil	Count	41	46	87
		% within GROUP	82.0%	92.0%	87.0%
Total	Count	50	50	100	
	% within GROUP	100.0%	100.0%	100.0%	

**Table 22**

**Chi-Square Tests**

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.287 <sup>a</sup>	3	.515
Likelihood Ratio	2.353	3	.502
Linear-by-Linear Association	2.150	1	.143
N of Valid Cases	100		

a. 6 cells (75.0%) have expected count less than 5. The minimum expected count is 1.50.

P-value for Chi Square test is 0.515-Not significant.



# **DISCUSSION**

## DISCUSSION

Elective endoscopic procedures can be satisfactorily done under both general anaesthesia and regional anaesthesia. Spinal anaesthesia is frequently used as a sole anaesthetic for procedures such as URSL, TURP, VL and OIU. It provides significant post operative analgesia.

Hyperbaric local anaesthetics are commonly used in subarachnoid block. But they cause significant hemodynamic changes in middle and elderly patients even with low concentrations. So an isobaric solution is a better alternative.

Using an opioid as adjuvant with local anaesthetic reduces the dose of local anaesthetic and also provides good post operative pain relief. Fentanyl is commonly used opioid additive.

So in this study we are comparing the effects of intrathecal low dose 0.5% isobaric Bupivacaine with Fentanyl and 0.5% isobaric Ropivacaine with Fentanyl.

In our group 1 patients received intrathecal 11.25 mg of 0.5% isobaric Bupivacaine with 12.5 microgram Fentanyl and group 2 patients received intrathecal 11.25 mg 0.5% isobaric Ropivacaine with 12.5 microgram Fentanyl. Onset and duration of sensory and motor blockade, hemodynamic

stability and quality of analgesia were observed and the parameters are subjected to 't test'.

## **ONSET OF SENSORY AND MOTOR BLOCK**

### **ARTICLE 1**

Acta Anaesthesiologica Scandinavica. 2005 Nov;49(10):1477-82.  
Compared the effects of intrathecal 10 mg of 0.5% plain (isobaric) bupivacaine and 10 mg of 0.5% plain ropivacaine with 15 microgram fentanyl in two groups and showed that time of onset of sensory and motor blockade is similar in both groups.

### **ARTICLE 2**

Mantouvalou M<sup>1</sup>

Compared the spinal effects of plain bupivacaine, ropivacaine and levobupivacaine in lower abdominal surgery and showed that the onset of motor block was significantly faster in the bupivacaine group compared with that in the ropivacaine group and almost the same of that in the levobupivacaine group ( $P < 0.05$ ).

In our study mean for onset of sensory block in group 1 is 2.62 and group 2 is 2.28 with mean difference 0.340 and  $P < 0.01$ . So time taken for sensory block upto T10 dermatomal level is earlier in Ropivacaine group (Group 2).

In our study mean for onset of motor block in group 1 is 4.86 and group 2 is 5.24 with mean difference -0.380 and  $P < 0.05$ . This shows onset of motor block is little earlier in Bupivacaine group (Group 1).

### **DURATION OF SENSORY BLOCK.**

According to Article 1 characteristics of sensory block is similar in both Bupivacaine and Ropivacaine group.

In Article 2 Ropivacaine presented a shorter duration of both motor and sensory block than Bupivacaine and Levobupivacaine ( $P < 0.05$ )

In our study mean duration of sensory block in group 1 is 139.10 and group 2 is 144.70 with mean difference -5.6 and  $P < 0.01$ . This shows duration of sensory block is longer in Ropivacaine group (Group 2) than Bupivacaine (Group 1).

### **DURATION OF MOTOR BLOCK.**

In the above stated Article 1 duration of motor block is shorter in Ropivacaine group with median, 126 min; interquartile range, 93-162 min compared to Bupivacaine group (median, 126 min; interquartile range, 93-162 min); difference between medians 71 mins with  $P = 0.003$ .

Article 2 states that Ropivacaine presented a shorter duration of both motor and sensory block than Bupivacaine and Levobupivacaine ( $P < 0.05\%$ ).

In our study mean duration of motor in group 1 is 140.50 and group 2 is 98.30 with mean difference 42.20 and  $P < 0.001$ . This shows duration of motor block is longer in Bupivacaine group (Group 1).

## **HEMODYNAMIC STABILITY**

According to Article 1 hemodynamic changes were similar between bupivacaine and ropivacaine groups.

In our study P value for baseline pulse rate, MAP, respiratory rate, SPO2 are 0.012, 0.661, 0.085, 0.843 respectively. P value for above parameters at 1, 3, 5, 10, 15, 30, 45, 60, 75, 90 and 120 mins lies between 0.05 and 0.1. So there were no significant hemodynamic changes observed between two groups.

## **QUALITY OF ANALGESIA**

Quality of analgesia is assessed by observing post operative visual analogue scale score at 1, 2, 3, 4, 5 and 6 hrs. There was no significant difference in pain experience in between two groups except in 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> hrs. P value of these hrs are  $< 0.05$ . Mean value for Ropivacaine group are less in these 2, 3 and 4 hrs. So quality of analgesia is comparatively better in Ropivacaine group (Group 2).

In group 1 side effects like hypotension and bradycardia were experienced by 5 and 4 patients respectively. In group 2 hypotension and bradycardia were experienced by 2 patients each. Incidence of hypotension and bradycardia is comparatively higher in bupivacaine group (Group 1).

# SUMMARY

## SUMMARY

Our study was conducted in elective endoscopic procedures like Trans Urethral Resection of Prostate, Vesicolitholapaxy, Ureteroscopic Stone Lithotripsy and Optical Internal Urethrostomy. The duration of endoscopic urological procedures does not exceed 1-1 ½ hrs. Spinal anaesthesia is commonly used for these procedures.

In our study, both isobaric Bupivacaine and isobaric Ropivacaine with Fentanyl provided adequate level of sensory blockade (T10) but Bupivacaine provides longer duration of motor blockade. Recovery from motor blockade is comparatively faster in Ropivacaine group.

Both the drugs have lesser hemodynamic effects. Quality of analgesia in post operative period was comparatively better with Ropivacaine.

Fentanyl additive was used in both the groups and it reduces the dose of local anesthetic.

Adverse effects like hypotension and bradycardia are fewer in both groups and are manageable.



# **CONCLUSION**

## **CONCLUSION**

We conclude from our study that low dose isobaric Ropivacaine with Fentanyl is a good alternative to isobaric Bupivacaine with Fentanyl in endoscopic urological procedures .Ropivacaine provides adequate level of sensory block and comparatively less duration of motor block which is enough for elective endoscopic urological procedures. This allows patients to ambulate early thereby reducing risks of venous stasis. It also provides good post operative pain relief.

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# **ANNEXURES**

## PROFORMA

DATE: ROLL NO: AIRWAY DEVICE:

NAME:

AGE: SEX: IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Ht: CVS: HB:

Wt: RS:

AIRWAY:MMC IID -

DENTITION -

PRE OP ASSESSMENT:

HISTORY: Any Co-morbid illness

H/O Documented Difficult Airway

H/O previous surgeries

H/O any drug allergy

MEASURES OF STUDY OUTCOME:

INTRAOPERATIVE HAEMODYNAMICS:

	HR	SBP	DBP	MAP	SPO2	RR
--	----	-----	-----	-----	------	----

PRE OP:

SUBARACHNOID BLOCK:

1 MIN:	15 min	75 min
3 MIN:	30 min	90 min
5 MIN:	45 min	120 min
10 MIN:	60 min	

ONSET TIME OF SENSORY BLOCKADE:

ONSET TIME OF MOTOR BLOCKADE:

COMPLICATIONS IN INTRA OPERATIVE PERIOD:

DURATION OF SENSORY BLOCKADE:

DURATION OF MOTOR BLOCKADE:

POST OPERATIVE PAIN SCORE **(1 to 6 hours)**

**INSTITUTIONAL ETHICS COMMITTEE**  
**MADRAS MEDICAL COLLEGE, CHENNAI-3**

EC Reg No.ECR/270/Inst./TN/2013  
Telephone No. 044 25305301  
Fax : 044 25363970

**CERTIFICATE OF APPROVAL**

To  
Dr. T.Muthukumar,  
Postgraduate M.D. (Anaesthesia),  
Madras Medical College,  
Chennai - 600 003.

Dear Dr. T.Muthukumar,


The Institutional Ethics Committee has considered your request and approved your study titled **"A Prospective randomized study to compare intrathecal isobaric bupivacaine with fentanyl and isobaric ropivacaine with fentanyl in patients undergoing elective endoscopic urological procedures."** No.45082014.

The following members of Ethics Committee were present in the meeting held on 05.08.2014 conducted at Madras Medical College, Chennai-3.

- |  |                      |
|--|----------------------|
| 1. Dr.C.Rajendran, M.D.,   | : Chairperson        |
| 2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3                            | : Deputy Chairperson |
| 3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3            | : Member Secretary   |
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| 9. Thiru S.Rameshkumar, Administrative Officer                   | : Lay Person         |
| 10.Thiru S.Govindasamy, B.A., B.L.,                              | : Lawyer             |
| 11.Tmt.Arnold Saulina, M.A., MSW.,                               | : Social Scientist   |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

  
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A COMPARITIVE STUDY OF INTRATHECAL ISOBARIC BUPIVACAINE WITH  
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### INTRODUCTION

Spinal anaesthesia is preferred over general anaesthesia for endoscopic urological procedures, because it facilitates early identification of symptoms caused by overhydration, Trans Urethral Resection of Prostate syndrome and bladder perforation.

Opioids are the commonly used adjuvants with local anaesthetics for intrathecal injections. They help to reduce the dosage of local anaesthetic without compromising the quality of analgesia. They also give better postoperative pain relief and so patient can be ambulated early which lowers the risk of postoperative venous thrombosis. Fentanyl is the frequently used opioid.

Commonly used local anaesthetic for sub arachnoid block is bupivacaine. But it has significant cardiotoxic properties. To overcome this side effect ropivacaine with less toxicity and long lasting effect was discovered.

Local anaesthetics are available as hypobaric, isobaric and hyperbaric solutions. Hyperbaric solutions are often used. They tend to settle in the dependant portion of the sac while isobaric solution will usually stay in vicinity where they are injected and diffuse slowly in all directions. Hence isobaric solutions produce less complications compared to hyperbaric.

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### INTRODUCTION

Spinal anaesthesia is preferred over general anaesthesia for endoscopic urological procedures, because it facilitates early identification of symptoms caused by overhydration, Trans Urethral Resection of Prostate syndrome and bladder perforation.

Opioids are the commonly used adjuncts with local anaesthetics for intrathecal injections. They help to reduce the dosage of local anaesthetic without compromising the quality of analgesia. They also give better postoperative pain relief and so patient can be ambulated early which lowers the risk of postoperative venous thrombosis. Fentanyl is the frequently used opioid.

Commonly used local anaesthetic for sub arachnoid block is bupivacaine. But it has significant cardiotoxic properties. To overcome this side effect ropivacaine with less toxicity and long lasting effect was discovered.

Local anaesthetics are available as hypobaric, isobaric and hyperbaric solutions. Hyperbaric solutions are often used. They tend to settle in the dependent portion of the sac while isobaric solution will usually stay in vicinity where they are injected and diffuse slowly in all directions. Hence isobaric solutions produce less complications compared to hyperbaric.

Isobaric anaesthetic injected in L2-L3 intervertebral space provides dense block at lower thoracic, lumbar and sacral areas. So it is ideally suited for endoscopic urological procedures which needs block upto T10 level. It results in partial sympathetic block with minimum hemodynamic changes.

In this prospective randomized control study, we are comparing the effects of intrathecal 0.5% isobaric bupivacaine with fentanyl and 0.5% isobaric ropivacaine with fentanyl in endoscopic urological procedures like Trans Urethral Resection of Prostate, Vesiculiolithotomy, Uretroscopic Stone Lithotripsy and Optical Internal Urethrostomy.

## **INFORMATION TO PARTICIPANTS**

**Investigator:**

**Name of the Participant:**

**Title:** *A Prospective, randomized study to compare intrathecal isobaric bupivacaine with fentanyl and isobaric ropivacaine with fentanyl in patients undergoing elective endoscopic urological procedures”.*

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare and study the safety and efficacy of subarachnoid block using bupivacaine with fentanyl and ropivacaine with fentanyl.

### **What is the Purpose of the Research:**

For elective endoscopic urological procedures, intrathecal bupivacaine with fentanyl and ropivacaine with fentanyl is given and patient is anaesthetised. In this study is done

To compare subarachnoid block using bupivacaine with fentanyl or ropivacaine with fentanyl in patients undergoing elective endoscopic urological procedures with respect to,

1. Intra operative hemodynamics ,
2. To compare onset and duration of sensory and motor blockade
3. Quality of analgesia

### **The Study Design:**

All the patients in the study will be divided into two groups.

Group1- pre operative subarachnoid block with bupivacaine with fentanyl .

Group 2- pre operative subarachnoid block with ropivacaine with fentanyl.



### **Benefits**

Subarachnoid block for urological procedures pre operatively reduces general anaesthetic complication, causes post operative pain relief, less likely to mask symptoms and signs of bladder perforation

### **Discomforts and risks**

Discomfort during block- this will be reduced by local infiltration.

Post dural puncture headache- this will be reduced by analgesics and intravenous fluid administration.

Hypotension, bradycardia may occur – emergency drugs are readily available.

This intervention has been shown to be well tolerated as shown by previous studies. And if you do not want to participate you will have alternative of setting the standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient

Patient Name:

Signature of the Investigator : \_\_\_\_\_

Name of the Investigator : \_\_\_\_\_



## ஆராய்ச்சி தகவல் தாள்

### ஆராய்ச்சி தலைப்பு

சிறுநீரகப் பாதை உள்நோக்கி மூலம் சிறுநீரகவியல் அறுவை சிகிச்சைக்கு கால் மற்றும் கீழ் வயிற்றுப்பகுதி மறத்துப்போகச் செய்வதற்காக முதுகு தண்டுவடத்தில் சப்அரக்னாய்டு பிளாக் மூலமாக பூபிவெக்கெய்ன் மற்றும் பென்டனைல் அல்லது ரொபிவெக்கெய்ன் மற்றும் பென்டனைல் மருந்து கலவையை செலுத்தி மறத்துப்போகச் செய்தலை ஒப்பிடுதல்

ஆராய்ச்சியாளரின் பெயர் : மரு.த.முத்துக்குமார்

பங்கேற்பாளர் பெயர் :

### ஆராய்ச்சியின் நோக்கம்

இவ்வாராய்ச்சியில் சிறுநீரக உட்பாதை அறுவை சிகிச்சைக்கு கால் மற்றும் கீழ் வயிற்றுப்பகுதி மறத்துப்போகச் செய்வதற்காக சப் அரக்னாய்டு பிளாக் மூலமாக ப்யூபிவெக்கெய்ன் மற்றும் பென்டனைல் அல்லது ரொபிவெக்கெய்ன் மற்றும் பென்டனைல் மருந்து கலவையை செலுத்தி பின்னர் அறுவை சிகிச்சை செய்வதை கீழ்க்கண்ட கோணங்களில் ஒப்பிடப்படுகிறது.

1. அறுவை சிகிச்சையின்போது இரத்த அழுத்தம் மற்றும் நாடித்துடிப்பின் மாற்றங்கள்.
2. கால் மற்றும் கீழ் வயிற்றுப்பகுதி செயலிழப்பின் தொடக்கம் மற்றும் முடிவு நேரம்.
3. வலி நிவாரண தன்மை

### ஆய்வின் தன்மை

பங்குபெறும் நோயாளிகள் இரண்டு குழுக்களாக பிரிக்கப்படுவர்.

குழு-1: சப்அரக்னாய்டு பிளாக் மூலமாக ப்யூபிவெக்கெய்ன் மற்றும் பென்டனைல் கொடுக்கப்படும்.

குழு-2: சப்அரக்னாய்டு பிளாக் மூலமாக ரொபிவெக்கெய்ன் மற்றும் பென்டனைல் கொடுக்கப்படும்.

அறுவை சிகிச்சையின் போது இரத்த அழுத்தம் மற்றும் நாடித்துடிப்பின் மாற்றங்கள் கண்காணிக்கப்படும்.

### ஆய்வினால் ஏற்படும் நன்மைகள்:

சப்அரக்னாய்டு பிளாக் மூலமாக இந்த மருந்துகள் செலுத்தப்படுவதன் மூலமாக நாடித்துடிப்பு மற்றும் இரத்த அழுத்தத்தில் சீரான மாற்றங்கள் இருக்கும்.

முழு மயக்கத்தின் பக்கவிளைவுகள் குறைக்கப்படும்.

அறுவை சிகிச்சைக்குப்பின் வலி நிவாரணம் நீடிக்கும்.

### உபாதைகள்:

குறைந்த இரத்த அழுத்தம், குறைந்த நாடித்துடிப்பு, குறைந்த சுவாச துடிப்பு ஏற்படலாம். அதற்கு மாற்று மருந்துகள் உடனடியாக கொடுக்கப்படும்.

நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விருப்பப்படவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் முறையில் மருந்து கொடுக்கப்படும் அல்லது முழு மயக்கம் கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம்.

சாட்சியின் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

பெயர்:

இடது கட்டைவிரல் ரேகை

நாள் :

பெயர்:

இடம் :

## **PATIENT CONSENT FORM**

Study title : "A Prospective, randomized study to compare intrathecal isobaric bupivacaine with fentanyl and isobaric ropivacaine with fentanyl in patients undergoing elective endoscopic urological procedures".

Study center:

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE,  
RAJIV GANDHI GOVT. GENERAL HOSPITAL,  
MADRAS MEDICAL COLLEGE,  
CHENNAI 3.

Participant name :                      Age:                      Sex:                      I.P.No:

I confirm that I have understood the purpose of procedure for the above study . I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator ,regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study . I understand that my identity will not be revealed in any information released to third parties or published , unless as required under the law . I agree not to restrict the use of any data or results that arise from the study .

Time:

Date:    Signature / thumb impression of patient

Place:    Patient name:

Signature of the investigator:

Name of the investigator:

## ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு

சிறுநீரகப் பாதை உள்நோக்கி மூலம் சிறுநீரகவியல் அறுவை சிகிச்சைக்கு கால் மற்றும் கீழ் வயிற்றுப்பகுதி மறத்துப்போகச் செய்வதற்காக முதுகு தண்டுவடத்தில் சப்அரக்னாய்டு பிளாக் மூலமாக பூபிவெக்கெய்ன் மற்றும் பென்டனைல் அல்லது ரொப்பிவெக்கெய்ன் மற்றும் பென்டனைல் மருந்து கலவையை செலுத்தி மறத்துப்போகச் செய்தலை ஒப்பிடுதல்

ஆராய்ச்சி நிலையம் : மயக்கவியல் துறை, சென்னை மருத்துவக் கல்லூரி,  
சென்னை - 600 003.

பங்கு பெறுவரின் பெயர் :  
பாலினம் :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

☐

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன்.

☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிகிறேன்.

☐

அறுவை சிகிச்சைக்கு கால் மற்றும் கீழ் வயிற்றுப்பகுதி மறத்துப்போகச் செய்வதற்கு முதுகு தண்டுவடத்தில் சப்அரக்னாய்டு பிளாக் மூலமாக பூபிவெக்கெய்ன் மற்றும் பென்டனைல் அல்லது ரொப்பிவெக்கெய்ன் மற்றும் பென்டனைல் மருந்து கலவையை செலுத்தி கால் மற்றும் கீழ் வயிற்றுப்பகுதி மறத்துப்போகச் செய்யப்படும் என்பதை அறிந்துகொண்டேன். இதனால் உடலுக்கு எந்தவிதமான உபாதைகளும் இருக்காது என்பதையும் அறிந்துகொண்டு இந்த ஆய்வில் பங்குபெற முழு மனதுடன் சம்மதிக்கிறேன்.

☐

நாள் :

இடம் :

கலந்து கொள்பவரின் கைரேகை/  
கையொப்பம்  
பெயர்

ஆய்வாளரின் கையொப்பம் :

ஆய்வாளரின் பெயர்

S.NO	AGE	SEX	BMI	ASA	SURGERY	BASELINE VITALS										PR (min)										SBP(min)										DBP (min)										AI																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
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FTEER SAB

MAP (min)															RR (min)										SpO2 (min)										FAILURE SIDE EFFECTS						POST OP VAS(HR)					
75	90	120	1	3	5	10	15	30	45	60	75	90	120	1	3	5	10	15	30	45	60	75	90	120	1	3	5	10	15	30	45	60	75	90	120											
80	80	80	92	83	80	84	90	87	84	86	94	93	95	15	15	16	16	14	16	15	14	15	15	14	99	99	99	99	99	99	99	99	98	99	100	0	0	1	2	2	3					
68	68	68	83	83	84	86	85	82	88	84	80	81	83	15	14	15	16	14	15	16	14	15	14	16	99	99	99	99	99	99	99	99	99	99	99	99	0	0	1	2	2	2				
76	74	74	83	79	80	80	84	82	80	80	86	83	84	15	15	15	14	15	16	14	15	16	17	16	100	98	99	98	99	99	99	99	99	99	98	99	0	0	1	2	3	4				
80	84	86	107	86	74	98	90	97	97	98	97	101	101	16	15	16	15	15	15	16	15	15	15	16	99	99	99	99	99	99	99	100	98	99	99	99	0	0	1	2	2	3				
74	80	86	101	79	70	112	98	87	83	87	88	93	103	14	15	14	14	14	16	17	14	16	14	15	99	98	99	99	99	99	99	99	99	99	99	99	0	1	2	2	3	3				
70	70	74	83	84	82	83	83	82	83	83	83	83	84	15	13	14	15	6	14	14	15	16	14	15	98	97	98	99	99	99	99	99	99	99	99	99	99	0	0	1	2	3	3			
74	74	74	81	81	73	73	74	83	83	87	87	87	87	14	14	15	16	15	15	14	14	15	15	16	99	99	99	99	99	99	99	99	99	99	98	99	0	0	1	2	3	4				
70	70	70	87	83	79	77	77	81	81	87	87	87	87	14	15	14	14	14	14	15	16	16	16	15	99	98	99	98	98	99	99	99	99	98	99	99	99	0	0	1	2	3	4			
84	84	84	91	83	81	76	79	77	84	93	97	97	97	15	14	15	15	15	14	14	15	15	15	14	99	99	99	99	99	99	98	99	98	99	99	99	1	1	1	1	2	3				
74	80	80	86	79	83	83	77	83	87	87	89	97	97	14	15	14	14	15	14	15	16	16	14	14	98	98	99	98	99	99	99	99	99	99	99	98	0	0	1	1	2	2				
76	76	76	77	77	73	73	77	83	87	87	89	89	89	15	15	16	16	15	15	15	16	16	17	16	100	97	100	99	99	99	99	99	99	99	98	99	0	0	1	1	2	2				
70	80	80	88	83	79	73	77	77	83	89	85	93	93	14	14	14	14	14	14	15	15	14	15	16	100	98	100	99	100	99	99	98	99	99	99	100	0	0	1	2	3	5				
74	74	74	78	77	73	73	77	79	81	83	87	87	87	15	15	15	15	15	14	15	16	16	16	16	99	99	99	98	100	99	99	99	99	99	99	100	0	0	1	1	3	4				
76	80	90	97	87	77	73	77	79	87	91	93	97	107	14	14	14	15	15	15	16	16	15	15	14	99	98	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99					
80	80	80	98	90	83	90	93	94	93	94	93	103	103	14	14	14	15	15	16	15	15	15	15	15	99	99	99	99	98	98	98	99	99	99	99	99	99	99	99							
80	86	86	95	79	73	104	88	87	91	95	93	103	104	14	13	13	13	14	15	15	16	15	14	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99							
82	90	90	93	90	83	90	93	80	93	90	98	103	103	14	14	14	15	16	16	16	16	15	15	15	98	99	99	99	99	99	99	99	98	99	99	98	99	98	99							
74	70	70	80	73	73	90	90	84	89	84	86	83	83	14	14	14	14	14	14	13	13	14	14	14	99	98	98	99	99	99	99	99	99	99	99	99	99	99	99							
90	90	101	91	87	79	75	83	87	97	107	107	107	107	15	14	15	15	14	14	14	14	14	15	15	99	99	98	98	99	99	99	99	98	99	98	99	99	99	99							
76	80	80	87	83	79	73	77	81	83	87	89	93	93	14	14	14	14	14	15	15	15	15	15	15	100	100	99	99	99	99	98	99	99	99	98	99	99	98	99	99						
74	74	74	83	73	77	81	83	87	87	87	87	87	87	15	16	15	15	15	15	14	14	14	14	15	99	99	99	99	100	98	99	99	98	99	99	99	99	99	99							
74	74	80	85	79	77	73	73	79	81	83	87	87	93	14	14	14	14	14	14	15	15	15	14	14	99	98	98	99	100	99	98	98	98	99	99	99	99	99	99							
70	70	76	86	80	84	82	80	84	84	86	83	83	91	14	15	14	14	15	14	14	14	14	14	15	15	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99						
70	76	80	83	81	77	73	73	79	81	83	83	89	93	15	15	15	15	15	14	14	14	14	15	15	99	99	99	99	100	99	99	99	99	99	99	99	99	99	99							
70	70	74	79	73	73	76	76	78	78	82	83	83	87	14	14	14	14	14	15	15	15	15	15	15	99	98	98	99	99	99	99	99	99	99	99	99	99	99	99							
60	60	70	79	77	73	77	79	77	73	73	73	73	83	14	14	14	15	15	15	15	15	14	14	14	99	99	99	100	99	98	99	99	99	99	99	98	99	99	98							
80	80	78	87	79	71	73	74	81	83	87	93	93	91	14	14	14	14	15	15	15	14	14	14	14	99	99	99	100	99	99	98	99	98	99	99	99	99	99	99							
76	80	84	87	82	77	77	79	82	83	87	89	93	97	15	14	15	14	15	14	13	14	15	14	14	99	99	99	100	99	99	99	98	99	99	99	99	99	99	99							
76	80	84	99	91	81	83	78	81	82	85	90	93	97	15	15	14	14	14	14	15	14	15	14	15	98	98	99	98	99	99	99	99	99	99	99	99	99	99	99							
80	80	84	81	77	77	78	77	80	83	87	92	92	97	14	14	14	14	14	14	14	14	14	14	14	100	97	99	99	99	99	99	99	99	99	99	99	99	99	99	99						
84	80	80	90	85	81	79	83	87	91	93	97	97	97	13	14	15	15	15	15	14	14	14	114	14	14	99	98	99	98	99	99	99	99	99	99	99	99	99	99							
72	74	76	85	81	78	75	73	78	81	83	87	88	89	14	14	15	14	14	15	15	16	16	14	15	99	99	100	99	99	99	99	99	99	99	99	99	99	99	99							
76	84	92	107	86	75	96	88	87	87	87	94	102	111	15	15	15	15	14	14	14	14	14	14	14	99	99	100	99	99	99	99	99	98	99	99	99	98	99	99	98						
68	70	72	91	89	85	81	79	73	81	79	82	83	86	14	14	14	14	14	14	15	15	15	15	15	99	99	99	99	99	99	98	99	99	99	99	99	99	99	99	99						
74	78	80	99	88	84	80	75	79	83	86	88	91	93	15	15	14	14	14	15	14	14	14	14	13	14	99	99	99	99	98	99	99	99	99	99	99	99	99	99							
70	74	76	96	83	79	77	73	75	79	81	83	87	89	14	15	15	15	14	14	14	14	14	14	15	15	100	99	98	99	99	99	99	99	99	99	99	99	99	99							
76	80	86	104	100	94	89	86	91	95	90	96	100	106	15	15	15	16	16	14	14	14	14	14	14	99	99	99	98	99	99	99	99	99	99	99	99	99	99	99							
76	78	80	97	90	87	85	83	79	81	83	89	91	93	15	15	15	15	15	14	14	14	14	14	14	99	100	99	98	100	98	99	99	99	99	99	99	99	99								
76	78	80	91	89	85	80	81	82	83	87	89	91	92	15	15	14	14	14	14	15	15	15	15	16	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99							
70	72	74	88	83	80	77	73	78	79	83	83	85	87	14	14	14	14	14	15	14	15	15	15	15	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99							
74	78	80	84	82	79	76	72	79	83	87	88	93	95	15	15	15	15	14	13	14	14	14	15	14	99	99	99	99	99	99	99	99	99	99	99	98	99	99	98							
66	68	68	87	85	76	75	73	77	79	81	80	81	81	14	14	1																														

S.NO	AGE	SEX	BMI	ASA	SURGERY	BASELINE VITALS										SENSORYI										MOTOR(min)										PR (min)										SBP(min)										DBP (min)									
						PR	SBP	DBP	MAP	RR	SpO2	ONSET	DURATION	ONSET	DURATION	1	3	5	10	15	30	45	60	75	90	120	1	3	5	10	15	30	45	60	75	90	120	1	3	5	10	15	30	45	60																				
GROUP 2						BASELINE VITALS																																																											
S.NO	AGE	SEX	BMI	ASA	SURGERY	PR	SBP	DBP	MAP	RR	SpO2	ONSET	DURATION	ONSET	DURATION	1	3	5	10	15	30	45	60	75	90	120	1	3	5	10	15	30	45	60	75	90	120	1	3	5	10	15	30	45	60																				
1	55 M	23.5 II			TURP	74	130	90	103	14	99	2	140	5	95	70	74	72	76	71	72	76	70	74	75	74	124	120	118	116	116	114	116	120	124	126	130	86	80	78	74	76	76	78	80																				
2	49 M		22 I		URS	80	124	76	92	14	99	3	145	6	100	76	70	68	74	71	76	72	71	74	76	71	120	116	114	114	112	114	120	122	124	126	128	72	70	68	66	64	68	70	72																				
3	32 M	24.5 I			URS	72	122	80	93	14	99	2	145	5	90	70	71	72	74	76	74	76	72	76	78	74	124	118	116	114	116	118	120	124	126	126	76	72	70	68	70	74	74	74																					
4	23 F	23 I			URS	74	118	78	91	15	98	2	135	5	95	70	68	66	64	72	74	70	76	74	72	71	114	110	106	106	108	110	112	114	114	118	74	70	68	64	68	70	72	74																					
5	60 M	23 II			TURP	76	146	88	107	16	100	2	130	5	100	72	70	64	62	72	74	76	74	78	74	74	144	134	130	132	130	134	136	138	140	144	146	84	80	78	76	74	74	76	78																				
6	54 F	24 II			VL	70	140	90	106	15	100	3	150	6	100	70	68	62	60	72	71	74	75	74	76	71	136	130	128	126	126	128	130	132	134	140	140	86	80	78	78	76	78	80	82																				
7	34 F	23.8 I			URS	82	126	78	94	14	99	2	155	5	105	82	76	74	72	78	76	74	72	74	76	74	130	120	116	114	118	120	124	126	130	130	74	72	68	64	68	70	74	76																					
8	48 M	22.5 I			URS	88	128	72	90	15	99	2	140	5	100	84	82	86	84	82	81	80	76	78	74	76	122	120	118	116	118	120	122	124	126	128	130	68	68	66	64	70	70	72	74																				
9	28 M	26 I			OIU	70	110	80	90	15	99	3	145	6	110	71	58	51	136	116	108	88	86	84	86	86	114	106	104	100	102	104	108	110	112	112	112	76	74	74	70	72	74	76	74																				
10	26 M	25.3 I			URS	74	116	74	88	15	99	2	145	5	95	72	76	74	78	74	76	72	76	74	75	76	112	108	106	106	104	106	110	112	114	116	120	72	68	68	66	68	70	72	72																				
11	66 M	22 II			TURP	84	154	96	115	16	99	2	155	5	95	80	74	70	70	72	76	74	72	74	76	74	142	136	134	130	132	134	134	136	136	136	140	90	86	84	80	76	78	78	80																				
12	64 M	20 II			TURP	80	148	84	105	14	99	2	150	4	110	76	70	68	74	71	75	76	72	74	74	72	144	138	134	130	130	132	134	136	138	140	144	82	78	74	72	70	74	76	76																				
13	41 M	25.6 I			URS	72	132	82	98	14	99	2	135	5	115	70	66	64	76	74	76	74	72	74	76	75	126	120	118	116	118	120	122	124	124	130	130	78	74	70	68	70	70	72	76																				
14	35 M	24.5 I			URS	74	124	70	98	14	99	3	130	7	90	70	64	60	72	74	76	74	75	74	75	74	120	114	112	108	106	104	108	110	112	114	114	66	60	60	60	62	64	66	70																				
15	45 M	23 I			URS	78	110	70	83	13	98	2	130	5	90	72	66	62	74	75	71	74	75	76	74	72	110	106	100	102	100	104	106	108	108	110	110	70	64	60	62	60	64	66	70																				
16	46 F	22.5 I			URS	76	124	68	86	15	100	2	145	5	95	76	70	68	66	70	72	74	74	72	72	75	122	116	114	112	110	114	116	120	122	124	124	64	60	62	62	60	64	66	70																				
17	43 M	24 I			URS	70	130	78	95	14	99	2	145	5	100	74	68	64	66	68	72	70	70	74	74	75	126	122	116	116	114	118	120	122	124	124	126	74	72	68	66	66	68	70	72																				
18	22 F	24 I			URS	70	108	72	84	13	99	2	140	5	105	66	64	60	60	64	66	68	66	68	68	68	110	106	104	100	102	102	104	104	106	108	110	70	66	64	60	62	62	60	64																				
19	32 M	24.3 I			URS	70	120	70	86	14	99	3	160	6	120	68	62	64	64	66	68	68	70	70	70	70	116	112	110	108	106	108	110	112	114	118	120	66	64	60	60	62	64	66	66																				
20	42 M	21.5 I			VL	74	126	76	94	14	99	2	155	5	100	66	58	50	128	112	98	90	80	76	74	74	120	116	114	112	110	112	114	116	120	120	74	70	68	66	64	66	68	68																					
21	58 M	26 I			URS	82	128	88	101	16	98	4	150	7	100	78	74	70	74	76	78	80	80	78	78	78	116	112	110	108	112	116	120	124	120	124	130	82	76	74	74	74	76	78	80																				
22	48 M	25 I			URS	82	118	80	93	15	99	2	150	5	90	76	72	68	66	70	72	74	74	76	76	78	116	110	106	104	108	110	112	114	116	120	120	76	72	68	66	68	70	74	76																				
23	36 M	23 I			URS	88	120	78	92	15	99	2	145	5	95	84	80	74	74	72	76	78	80	80	82	82	114	108	104	100	100	106	108	110	114	116	120	74	70	66	64	60	64	68	68																				
24	18 M	25.8 I			OIU	88	110	70	83	14	99	3	160	6	95	80	76	72	68	66	70	72	72	74	78	80	114	106	100	102	100	104	106	108	110	114	116	70	68	64	62	60	64	66	66																				
25	59 M	24 II			TURP	86	146	94	111	16	99	2	145	5	95	82	78	74	70	72	70	72	74	76	76	75	140	130	126	120	124	126	124	130	136	140	140	90	84	80	76	80	82	84	86																				
26	63 M	21.6 II			TURP	70	148	88	108	15	99	2	135	5	110	80	74	72	68	66	70	76	78	80	80	80	146	134	124	124	128	130	132	136	140	146	154	86	80	76	74	74	76	74	78																				
27	56 M	25.9 II			TURP	70	154	92	112	14	99	4	130	6	115	74	90	104	96	88	80	76	72	70	74	74	140	110	94	132	128	120	116	124	132	138	140	92	70	64	72	74	70	68	68																				
28	70 M	24.6 II			TURP	80	138	86	103	13	99	2	140	4	90	76	70	70	68	72	74	74	76	76	78	78	134	126	122	120	122	118	124	126	128	130	132	84	78	74	70	68	68	70	74																				
29	26 F	22 I			URS	86	110	70	83	12	100	2	140	4	95	80	76	72	68	66	70	70	72	74	76	76	112	106	100	102	104	106	108	110	114	114	118	72	66	64	64	64	66	68	70																				
30	38 F	25 I			URS	74	124	82	96	15	99	2	145	5	95	70	68	66	68	66	70	72	72	74	74	74	120	112	108	106	104	112	114	118	120	124	130	80	74	68	66	64	66	70	72																				
31	48 M	22 I			URS	76	126	78	94	17	99	4	145	6	95	70	70	66	68	66	68	70	70	72	72	74	124	118	112	114	110	108	114	116	118	120	126	74	72	66	64	66	68	70	72																				
32	35 M	23 I			URS	78	130	80	97	16	99	3	135	7	100	76	74	70	74	76	72	74	76	78	74	76	126	116	112	114	118	120	124	126	124	126	130	74	68	70	72	76	74	76	78																				
33	34 M	25.4 I			URS	74	120	80	93	14	99	2	155	6	100	70	68	64	72	76	74	74	76	78	72	76	114	110	106	104	106	108	110	112	114	120	124	74	72	66	64	66	70	70	72																				
34	41 M	22.9 I			URS	76	124	78	93	17	99	2	150	5	100	74	70	66	70	74	76	74	75	76	74	78	122	116	114	110	106	108	110	114	116	118	124	72	68	64	60	62	66	70	72																				
35	39 F	23.5 II			VL	78	122	76	91	14	99	2	150	6	95	72	64	60	66	74	74</																																												

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